## REMARKS

### I. Status of the claims and Withdrawal of Reliance on General Properties and Data for Other Compounds Set Forth in Specification

Claims 39-40 and 42-43 have been amended to be placed in independent claim format, and claims 44-71 have been cancelled herein. There is written description support for changing dependent claims to independent form. Accordingly, claims 38-43, as amended, are pending and currently stand rejected.

As originally filed, claim 1 was broadly directed to a genus of compounds. As prosecution has proceeded, the claimed invention has become more narrowly directed, as recited in pending claims 38-43, as amended. The undersigned in reviewing the specification has noted that certain statements broadly aver that the compounds of the invention have certain properties. For example, at the beginning of the specification it is stated:

> The invention concerns certain novel quinazoline derivatives, or pharmaceutically acceptable salts thereof, which possess anti-tumour activity and are accordingly useful in methods of treatment of the human or animal body. The invention also concerns processes for the manufacture of said quinazoline derivatives, to pharmaceutical compositions containing them and to their use in therapeutic methods, for example in the manufacture of medicaments for use in the prevention or treatment of solid tumour disease in a warm-blooded animal such as man.

Later, the specification talks about specific activity tests and reports results for certain compounds not falling within the literal scope of claims 38-43 as follows:

Although the pharmacological properties of the compounds of the Formula I vary with structural change as expected, in general activity possessed by compounds of the Formula I, may be demonstrated at the following concentrations or doses in one or more of the above tests:-

Test (a):- $IC_{50}$ in the range, for example, 0.001 - 10 $\mu$M;

Test (b):- $IC_{50}$ in the range, for example, 0.001 - 10 $\mu$M;

Test (e):- $IC_{50}$ in the range, for example, 0.001 - 10 $\mu$M;

Test (c):- activity in the range, for example, 1-200 mg/kg/day;

By way of example, Table A illustrates the activity of representative compounds according to the invention. Column 2 of Table A shows $IC_{50}$ data from Test (a) for the inhibition of EGFR tyrosine kinase protein phosphorylation; column 3 shows $IC_{50}$ data from Test (a) for the inhibition of erbB2 tyrosine kinase protein phosphorylation; column 4 shows $IC_{50}$ data for inhibition of proliferation of KB cells in Test (b) described above; and column 5 shows $IC_{50}$ data for inhibition of phosphorylation of erbB2 in a MCF7 derived cell line in Test (e) described above:

Table A

| **Example Number** | **$IC_{50}$ ($\mu$M) Test (a): Inhibition of EGFR tyrosine kinase protein phosphorylation** | **$IC_{50}$ ($\mu$M) Test (a): Inhibition of erbB2 tyrosine kinase protein phosphorylation** | **$IC_{50}$ ($\mu$M) Test (b): EGFR driven KB cell proliferation assay** | **$IC_{50}$ ($\mu$M) Test (e): Inhibition of erbB2 tyrosine kinase protein phosphorylation** |
|---|---|---|---|---|
| 5 | 0.004 | 0.047 | 0.009 | 0.006 |
| 7 | 0.003 | 0.013 | 0.017 | 0.014 |
| 10 | 0.004 | 0.010 | - | 0.013 |

See also p. 52, lines 1-3 for other general statements.

Regarding the subject matter of claims 38-43, as amended, Applicants do not need to rely on such general statements and data for other compounds. Hence,

Applicants expressly withdraw reliance on all such general statements and test results in the specification.

Applicants have no reason to doubt that the subject matter of claims 38-43, as amended, possesses practical anti-tumor utility. But in view of the current plague of inequitable conduct allegations in U.S.litigation and in an overabundance of caution, Applicants disavow, as arguments for patentability, any representation of properties in the specification extending beyond the specific subject matter of claims 38-43, as amended.

**II. Substance of Interview Under 37 C.F.R. § 1.133(b)**

Further to the Interview on March 5, 2009, and the Examiner's Interview Summary mailed March 18, 2009, Applicants are, in an abundance of caution, re-submitting a recordation of the Substance of the Interview. To ensure timeliness, Applicants separately filed on April 3, 2009, a Substance of the Interview.

M.P.E.P. § 713.04 provides eight items (A-H) that should be addressed in Applicants' submission of the substance of the interview. Applicants' submissions regarding each of those items follow.

(A) The Exhibit shown at the interview is attached hereto as Exhibit A.

(B) The claims were generally all discussed.

(C) The prior art discussed, Bradbury (WO 03/082831), is identified in the attached Exhibit A.

(D) The Interview Summary indicates that "Applicant provided a presentation which included a proposed set of new claims to be filed by way of an RCE." However, there was some degree of misunderstanding as Applicants' representatives merely

indicated that the non-elected claims would be cancelled in an RCE, as required by the Office in the final Office Action, but that the elected claims 38-43 would be re-presented without amendment. Upon further reflection, however, as noted above, Applicants have, subsequent to filing on April 3 the Substance of the Interview, decided to amend claims 39-40 and 42-43, as set forth above.

(E) The arguments discussed are provided in the attached Exhibit A. Furthermore, during the interview, the issue of obviousness-type double patenting of the pending claims in view of the pending claims in Bradbury Application No. 12/147,250 (the currently-pending continuation of the U.S. national phase application of WO 03/082831) and Example 11 thereof was raised. Applicants disagreed that there is an issue of obviousness-type double patenting.

Also discussed during the interview was the issue of interference estoppel in view of Applicants' lost counts of Interference Nos. 105,595 and 105,596. Applicants disagreed that there is any issue of interference estoppel.

(F) The pertinent matters discussed are provided in the attached Exhibit A.

(G) No agreement was reached at the interview.

(H) This interview was in person, so this item does not apply.

**III. Rejection Under 35 U.S.C. § 103(a)**

**A. Bradbury Is Not Effective Under 35 U.S.C. § 102(a)/103**

Claims 38-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 03/082831 ("Bradbury"). The Office Action asserts that one having ordinary skill in the art would have been motivated to select and then modify Bradbury's Example 11.

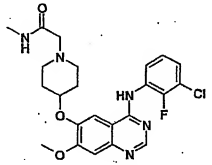
Applicants respectfully disagree and traverse that rejection. Solely to advance, prosecution, however, Applicants will now demonstrate that Bradbury is not prior art.

Bradbury didn't publish until October 9, 2003. That publication, occurring less than one year before the U.S. filing date of the present application, September 15, 2004, would at best be § 102(a)/103 prior art against the present claims. But that possible § 102(a)/103 prior art effect is defeated.

That is because the pending claims are entitled to benefit of priority of the filing date of EP03292309.6, which was filed September 19, 2003, some 20 days before Bradbury published. In particular, that EP application contains § 112, 1st paragraph, written description support for compound claims 38-40, as amended, of the present application. For example, Example 1 recites:

Example 1

Preparation of 4-(3-Chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl)piperidin-4-yl]methoxy}quinazoline



2-Chloro-N-methylacetamide (32 mg, 0.3 mmol) was added dropwise to a mixture of 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-[(piperidin-4-yl)oxy]quinazoline (120 mg, 0.3 mmol), potassium iodide (16 mg, 0.1 mmol), and potassium carbonate (50 mg, 0.36 mmol) in acetonitrile (5 ml). The mixture was heated at reflux for one hour. After evaporation of the solvents under vacuum, the residue was taken up in dichloromethane. The organic solution was washed with water and brine, dried over magnesium sulfate. After evaporation of the solvents under vacuum, the residue was purified by chromatography on silica gel (eluant: 1% to 2% 7N methanolic ammonia in dichloromethane) to give the title compound as a white solid (85 mg, 60%).

Thus, there is written description support for the compound recited in claim 38.[1] And page 6, line 25, of EP03292309.6 refers to and thus supports pharmaceutically acceptable salts.

[1] Example 1 recites that 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl) piperidin-4-yl]-**meth**oxy}quinazoline was formed, as opposed to the claimed 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl) piperidin-4-yl]-**oxy**}quinazoline. The structure and the starting materials (4-(3-chloro-2-fluoroanilino)-7-methoxy-6-(piperidin-4-yl)**oxy**]quinazoline), however, show that the title was simply an error that would have been obvious to one of ordinary skill in the art, and that the presently claimed compound, 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl) piperidin-4-yl]-**oxy**}quinazoline, was prepared and disclosed in that prior application.

EP03292309.6 also contains § 112 support for the pending pharmaceutical composition claims, claims 41-43, as amended. For example, see page 35, line 26 et. seq., and original claim 19 of EP03292309.6 recites:

> 19. A pharmaceutical composition which comprises a quinazoline derivative of the Formula I, or a pharmaceutically-acceptable salt thereof, as defined in any one of claims 1 to 17 in association with a pharmaceutically-acceptable diluent or carrier.

Nor is there any issue of enablement or best mode in EP03292309.6 for the subject matter of claims 38-43, as amended. Accordingly, there is full § 112 support for all of the pending claims 38-43, as amended, in EP03292309.6.

Thus, the effective filing date of the present application for purposes of avoiding prior art is the date that EP03292309.6 was filed, September 19, 2003. That date is before the October 9, 2003 publication date of Bradbury. Hence, any possible § 102(a)/103 prior art effect of Bradbury is defeated.

**B. Bradbury Is Disqualified As § 102(e)/103(a) Prior Art Under 35 U.S.C.§ 103(c)**

The effective U.S. filing date of Bradbury is its PCT filing date, March 26, 2003. Although Bradbury claims priority to three GB applications, "[t]he effective date of a domestic patent, when used as a reference, is not the foreign filing date to which the application for patent may have been entitled under 35 U.S.C. § 119(a) during examination. *In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966). Therefore, the date to be overcome under 37 CFR 1.131 is the effective U.S. filing date, not the foreign priority date." M.P.E.P. § 715(III)(A).

The Bradbury effective U.S. filing date, i.e., the PCT filing date, March 26, 2003, is not antedated by the EP priority date of September 19, 2003 of the instant application. But Bradbury nowhere discloses the compound/salt of claim 38. Hence, Bradbury would not be prior art under § 102(e), but at best could be relevant under § 102(e)/103(a).

But Bradbury is not relevant under § 102(e)/103(a). Effective November 29, 1999, subject matter which was prior art under one or more of 35 U.S.C. § 102(e), (f), and (g)/103 is disqualified under § 103(c) as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

In the present case, Bradbury and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to AstraZeneca. Accordingly, Bradbury, a possible 35 U.S.C. § 102(e)/103 reference, is disqualified as 35 U.S.C. § 103(a) prior art against the claimed invention under § 103(c).

## IV. Additional Comments

### A. No Interference Estoppel

As noted above, at the interview, the issue of interference estoppel was raised, and Applicants were of the view that none applied. Herein, Applicants set forth their reasoning as to why there is no interference estoppel.

In the Information Disclosure Statement filed on July 14, 2008, Applicants brought to the attention of the Examiner Patent Interference Nos. 105,595 McK and

105,596 McK. As noted therein, those interferences were initiated and consolidated by the Declaration dated November 21, 2007, and involved AZ's US Application No. 10/508,675 (the US National Phase of Bradbury) and Boehringer Ingelheim's (hereinafter referred to as "BI") U.S. Patent Nos. 6,924,285 and 7,119,084, respectively.

On June 17, 2008, the Board issued a single Judgment applicable to both those interferences, wherein the Board ordered that judgment on priority on all Counts was awarded against AZ's US Application No. 10/508,675. All claims of that application involved in the interference, i.e. claims 23-25, were finally refused. A copy of that Decision is already of record.

At the interview, as noted above, the issue of interference estoppel was raised. There are two main types of interference estoppel. First, a losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). Second, a losing party is procedurally barred from seeking relief that could have been, but was not, sought in the interference. 37 CFR § 41.127(a)(1); *Ex parte Kimura*, 55 USPQ2d 1537 (Bd. Pat. App. & Inter. 2000). As will be explained, neither type of interference estoppel applies to claims 38-43, as amended.

**1. Claims 38-43, As Amended, Would Not Have Been Anticipated or Rendered Obvious by the Subject Matter of the Lost Counts**

In the present case, Applicants' present claims 38-43, as amended, would not have been anticipated or rendered obvious by the subject matter of the lost count. There is no anticipation. More specifically, "[w]hen the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and

combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated." M.P.E.P. §2131.02 (*citing Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)). "If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated." M.P.E.P. §2131.02 (internal citation omitted). That is not the case here.

Here, the counts are very broad, encompassing millions of compounds[2], and one of ordinary skill in the art would not have been able to "at once envisage" the single species and salts thereof recited in claims 38-43, as amended. *See also Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008) (copy submitted herewith). Accordingly, the lost counts fail to anticipate the present claims.

Regarding obviousness, the present claims 38-43, as amended, encompass a compound chosen from a single species and its salts, while the lost counts are drawn to broad formulaic genera, encompassing, as noted above, millions of compounds.

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[2] Count 1 was an alternative McKelvey count, reciting claim 1 of the BI patent or claim 23 of the AZ application in interferences. AZ claim 23 itself is estimated to cover millions of species, calculated as follows. Since $G^1$ and $G^2$ can be halogeno (i.e., any of fluoro, chloro, bromo, iodo), that presents 16 options for $G^1$ and $G^2$. $X^1$ may be a direct bond or O. Those two options double the number of possible compounds when taking the possibilities for $G^1$ and $G^2$ into account. Accordingly, there are 32 possible compounds, just taking $G^1$, $G^2$, and $X^1$ into account. $R^1$ may be chosen from 1-6C alkyl, thus providing 6 more choices, not counting branching, and thereby increasing the number of possible compounds of claim 23 by 6 times (32 x 6 = 192). However, $R^1$ may be optionally substituted by "one or more" substituents selected from hydroxy and/or one of 60 different substituents. Accordingly, taking into account that $R^1$ can be 1-6C alkyl and can be unsubstituted, substituted, or multiply substituted, the number of possible compounds escalates to thousands. Further increasing the number of possible compounds are the options for $Q^1$, which may be any (3-7C)cycloalkyl or heterocyclyl, thus encompassing hundreds of possible ring structures. The number of possible compounds thus escalates to at least hundreds of thousands. Then, $Q^1$ may optionally bear up to 3 substituents, which may be the same or different, and may be selected from 4 groups and 17 different classes of compounds, which may themselves be further substituted. Accordingly, $Q^1$ may be substituted with 0, 1, 2, or 3 substituents chosen from among thousands. Thus, claim 23 appears to encompass millions of different compounds. The BI claim 1 alternative appears to encompass even more compounds.

This is not an "obvious to try" or even an "identified predictable solution" situation in the post-*KSR* world. As explained in *Eisai Co. Ltd. v. Teva Pharmaceuticals USA, Inc.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (internal citations omitted) (emphasis added):

> The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. **First**, *KSR* assumes a **starting reference point** or points in the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. **Second**, *KSR* presupposes that the record up to the time of invention would give some **reasons**, available within the knowledge of one of skill in the art, **to make particular modifications to achieve the claimed compound. Third**, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some **reasons for narrowing the prior art universe to a 'finite number of identified, predictable solutions**....'

"The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." M.P.E.P. § 2144.08 (*citing In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious.") and also citing *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992) ("Federal Circuit "has decline[d] to extract . . . the rule that . . . regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it."))[3]

"To the extent an art is unpredictable, as the chemical arts often are, *KSR's* focus on ... 'identified, predictable solutions' may present a difficult hurdle because potential solutions are less likely to be genuinely predictable. In other words, *post-KSR,* a prima

[3] Post-*KSR, Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.,* 492 F.3d 1350, 1356; (Fed. Cir. 2007) reaffirmed *In re Jones,* 958 F.2d 347 (Fed. Cir. 1992) and *In re Deuel,* 51 F.3d 1552 (Fed. Cir. 1995) which, in turn at 51 F.3d 1559, reaffirmed *In re Baird,* 16 F.3d 380 (Fed. Cir. 1994).

facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound." *Eisai,,* 533 F.3d at 1359. Furthermore, "in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda,* 492 F.3d at 1357. And no reason has been provided by the Office why one of ordinary skill in the art would have selected the claimed species recited in claims 38-43, as amended.

In *In re Baird,* noted with approval in M.P.E.P. § 2144.08 and, as stated in the footnote, effectively approved post-*KSR*, the application at issue claimed a flash fusible toner "comprising a binder resin which is a bisphenol A polyester containing an aliphatic dicarboxylic acid selected from the group consisting of succinic acid, glutaric acid, and adipic acid."

The prior art related to developer compositions comprised of, *inter alia,* a polymeric esterification product of a dicarboxylic acid and a diphenol having a generic formula that contained a broad range of variables and thus encompassed a large number of different diphenols, one of which was bisphenol A. In addition, the prior art patent disclosed a subgenus of 20 aliphatic dicarboxylic acids, including those claimed in Baird.

In other words, the claimed "bisphenol A polyester containing an aliphatic dicarboxylic acid selected from the group consisting of succinic acid, glutaric acid, and adipic acid" could be obtained by choosing specific variables from the broad genus of the prior art. The Board found the claim to be obvious, reasoning that "the fact that [the

claimed] binder resin is clearly encompassed by the generic disclosure of [the prior art] . . . provides ample motivation for the selection of [the claimed composition]."

The Federal Circuit, noting that what a reference teaches is a question of fact, reversed the Board's rejection, reasoning that the fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. *In re Baird,* 16 F.3d 380 at 382 The Court estimated that the prior art reference encompassed more than 100 million different phenols, only one of which was the bisphenol A recited in the claim of Baird. *Id* And there was nothing in the prior art that suggested selecting those variables; rather, the selections suggested taught away from the claimed compounds. *Id.* at 382-83.

As is the case here, the Court acknowledged that the prior art (here, the lost counts) "unquestionably encompasses" the Baird species when specific variables were chosen. But also as is the case here, just as in *Baird*, there was nothing in the prior art [here the lost counts] that would have lead one to select such variables. And *Takeda*, *supra*, emphasized that the prior art needs to suggest making the specific molecular modifcations necessary to achieve the claimed inventuion, citing *In re Jones,* 958 F.2d 347 (Fed. Cir. 1992).

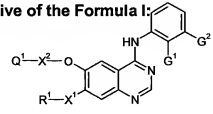
In the present case, as shown more specifically by the copies of slides presented at the interview (which are attached to the Interview Summary and hereto as Exhibit A) and in a similar showing on the following page,[4] the present claim 38 is patentably distinct over the lost AZ interference claim 23, an alternative part of the lost

[4] The following page shows in highlighting substituents in present claim 38 that were in the lost count of AZ's claim 23. The interview slide used red type font, which does not scan as red, thus the distinction was lost. It is believed that the colors used herein will show a distinction when scanned by the USPTO.

count, due to the breadth of the lost count claim, and, as in *Baird*, the total lack of suggestion in the lost count to select the presently claimed compound/salts recited in claims 38-43, as amended.

**Pending AZ Claim 38 Compared to AZ Claim 23 From the Interference (Overlap in highlight)**

**23. A quinazoline derivative of the Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is halogeno;**

**$X^1$ is a direct bond or O;**

**$R^1$ is (1-[[4]]6C)alkyl, wherein the (1-6C)alkyl group is optionally substituted by one or more substituents, which may be the same or different, selected from hydroxy, and/or a substituent selected from amino, (1-6C)alkoxy, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, (2-6C)alkanoylamino, and (1-6C)alkanesulphonylamino;**

**$X^2$ is a direct bond;**

**$Q^1$ is (3-7C)cycloalkyl or heterocyclyl, wherein $Q^1$ optionally bears 1, 2, or 3 substituents, which may be the same or different, selected from cyano, amino, carbamoyl, (1-6C)alkyl, (1-6C)alkylsulphonyl, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, (2-6C)alkanoyl, (2-6C)alkanoylamino, N-(1-6C)alkyl(2-6C)alkanoylamino, sulphamoyl, N-(1-6C)alkylsulphamoyl, N,N-di[(1-6C)alkyl]sulphamoyl, (1-6C)alkanesulfonylamino, N-(1-6C)alkyl-(1-6C)alkanesulfonylamino, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and (2-6C)alkanoylamino(1-6C)alkyl, and**

**wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from halogeno and hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;**
**and wherein any heterocyclyl group within the $Q^1$-$X^2$- group optionally bears 1 oxo (=O) substituent;**

**or a pharmaceutically acceptable salt thereof.**

It can be seen that compared to AZ interference claim 23, claim 38, reading as follows, is even more narrow than indicated in the above highlighting:

> A compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl)piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts.

As can be seen, $G^1$ and $G^2$ in the highlighting above are not halogeno in general in claim 38 but respectively fluoro and chloro. Furthermore, in AZ claim 23 of the lost count, $Q^1$ may be any (3-7C)cycloalkyl or heterocyclyl, thus encompassing hundreds of possible ring structures. In contrast, $Q^1$ in present claim 38 is a particular heterocyclyl, specifically piperidin-4-yl.

Finally, in AZ claim 23 of the lost count, $Q^1$ may optionally bear up to 3 substituents, which may be the same or different. And those substituents may be selected from 4 groups and 17 different classes of compounds, which may themselves be further substituted. Accordingly, $Q^1$ may be substituted with 0, 1, 2, or 3 substituents chosen from among thousands. However, in present claim 38, $Q^1$ bears the single substituent N-methylcarbamoylmethyl. In other words, out of the millions of possibilities in AZ claim 23, claim 38 recites a single species and salts thereof.

Accordingly, in view of M.P.E.P. § 2144.08, due to the breadth of the lost count claims, and the lack of any suggestion in AZ claim 23 to select the presently claimed species of claim 38, claim 38 is patentably distinct, i.e., non-obvious, over claim 23.

Lost AZ interference claim 24 (a composition claim) and lost AZ interference claim 25 (a method claim) are of the same scope as lost AZ interference claim 23 with respect to the compound or salt. In other words, the compound/salts recited in lost claims 24 and 25 is the same as recited in lost claim 23. Accordingly, it is Applicants'

position that present claim 38 is patentably distinct over lost AZ interference claims 24 and 25 for the same reasons it is patentably distinct over lost AZ interference claim 23.

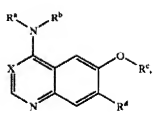
Applicants' also believe that the present claims 39-43, as amended, are no broader in compound or salt scope than present claim 38 and thus claims 39-43, as amended, are patentably distinct for the same reasons that claim 38 is patentably distinct over lost AZ interference claims 23-25.

At the Interview, as with the lost AZ claim 23, Applicants' representatives showed, in a colored slide similar to that on the following page,[5] how the present claim 38 is patentably distinct over the enormously broad lost BI interference claim 1, an alternative part of the lost count, due to the breadth of the lost count claims, and the lack of suggestion to select the presently claimed species in any of the claims of the lost counts. Out of an abundance of caution, Applicants will also address lost BI interference claim 2 herein.

[5] The following page shows in highlighting substituents in present claim 38 that were in the lost count of BI's claim 1. The interview slide used red type font, which does not scan as red, thus the distinction was lost. It is believed that the colors used herein will show a distinction when scanned by the USPTO.

**Presently Pending AZ Claim 38 Compared to BI Claim 1 of the Interference (Overlap in Highlight)**

**1. A compound of the general formula**



(I)

**wherein**
**$R^a$ denotes a hydrogen atom or a C1-4-alkyl group,**

**$R^b$ denotes a phenyl or 1-phenylethyl group, wherein the phenyl nucleus is substituted in each case by the groups $R^1$ to $R^3$, while**
**$R^1$ and $R^2$, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom, a C1-4-alkyl, hydroxy, C1-4-alkoxy, C2-3-alkenyl or C2-3-alkynyl group, an aryl, aryloxy, arylmethyl or arylmethoxy group, a heteroaryl, heteroaryloxy, heteroarylmethyl or heteroarylmethoxy group, a methyl or methoxy group substituted by 1 to 3 fluorine atoms or a cyano, nitro or amino group, and**
**$R^3$ denotes a hydrogen, fluorine, chlorine or bromine atom or a methyl or trifluoromethyl group,**

**Rc denotes**
**- a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R4-N-R5, while**
**R4 denotes a hydrogen atom or a C1-3-alkyl group and**
**R5 denotes a hydrogen atom or a C1-3-alkyl group,**
**an aminocarbonyl-C1-3-alkyl, C1-3-alkylaminocarbonyl-C1-3-alkyl, di-(C1-3-alkyl)aminocarbonyl-C1-3-alkyl, pyrrolidin-1-ylcarbonyl-C1-3-alkyl, piperidin-1-ylcarbonyl-C1-3-alkyl, homopiperidin-1-ylcarbonyl-C1-3-alkyl, morpholin-4-ylcarbonyl-C1-3-alkyl, homomorpholin-4-ylcarbonyl-C1-3-alkyl, piperazin-1-ylcarbonyl-C1-3-alkyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl-C1-3-alkyl, homopiperazin-1-ylcarbonyl-C1-3-alkyl or a 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl-C1-3-alkyl group,**

a hydroxy-C2-4-alkyl, C1-3-alkyloxy-C2-4-alkyl, C1-4-alkyloxy-carbonylamino-C2-4-alkyl, amino-C2-4-alkyl, C1-3-alkylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-C2-4-alkyl, C1-3-alkylcarbonylamino-C2-4-alkyl, aminocarbonylamino-C2-4-alkyl, C1-3-alkylaminocarbonylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-carbonylamino-C2-4-alkyl, pyrrolidin-1-ylcarbonylamino-C2-4-alkyl, piperidin-1-ylcarbonylamino-C2-4-alkyl, morpholin-4-ylcarbonylamino-C2-4-alkyl, C1-3-alkylsulphonyl-C2-4-alkyl or a C1-3-alkylsulphonylamino-C2-4-alkyl group,
a (2-oxo-pyrrolidin-1-yl)-C2-4-alkyl, (2-oxopiperidin-1-yl)-C2-4-alkyl, (3-oxo-morpholin-4-yl)-C2-4-alkyl, (2-oxo-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-3-C1-3-alkyl-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-hexahydropyrimidin-1-yl)-C2-4-alkyl or a (2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl)-C2-4-alkyl group,
a C1-4-alkylsulphonyl, chloro-C1-4-alkylsulphonyl, bromo-C1-4-alkylsulphonyl, amino-C1-4-alkylsulphonyl, C1-3-alkylamino-C1-4-alkylsulphonyl, di-(C1-3-alkyl)amino-C1-4-alkylsulphonyl, (pyrrolidin-1-yl)-C1-4-alkylsulphonyl, (piperidin-1-yl)-C1-4-alkylsulphonyl, (homopiperidin-1-yl)-C1-4-alkylsulphonyl, (morpholin-4-yl)-C1-4-alkylsulphonyl, (homomorpholin-4-yl)-C1-4-alkylsulphonyl, (piperazin-1-yl)-C1-4-alkylsulphonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkylsulphonyl, (homopiperazin-1-yl)-C1-4-alkylsulphonyl or a (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkylsulphonyl group, a C1-4-alkyloxycarbonyl group,
a formyl, C1-4-alkyl-carbonyl, C1-3-alkyloxy-C1-4-alkyl-carbonyl, tetrahydrofuranylcarbonyl, tetrahydropyranylcarbonyl, amino-C1-4-alkyl-carbonyl, C1-3-alkylamino-C1-4-alkyl-carbonyl, di-(C1-3-alkyl)amino-C1-4-alkyl-carbonyl, pyrrolidin-1-yl-C1-4-alkyl-carbonyl, piperidin-1-yl-C1-4-alkyl-carbonyl, (homopiperidin-1-yl)-C1-4-alkyl-carbonyl, morpholin-4-yl-C1-4-alkyl-carbonyl, (homomorpholin-4-yl)-C1-4-alkyl-carbonyl, (piperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkyl-carbonyl, (homopiperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkyl-carbonyl or a C1-3-alkylsulphonyl-C1-4-alkyl-carbonyl group,
a cyano, aminocarbonyl, C1-3-alkyl-aminocarbonyl, di-(C1-3-alkyl)aminocarbonyl, (C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, N-(C1-3-alkyl)-N-(C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, arylaminocarbonyl, pyrrolidin-1-ylcarbonyl, piperidin-1-ylcarbonyl, homopiperidin-1-ylcarbonyl, morpholin-4-ylcarbonyl, homomorpholin-4-ylcarbonyl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-ylcarbonyl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-ylcarbonyl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-ylcarbonyl, piperazin-1-ylcarbonyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl, homopiperazin-1-ylcarbonyl, 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl, aminosulphonyl, C1-3-alkyl-aminosulphonyl, di-(C1-3-alkyl)amino-sulphonyl, pyrrolidin-1-yl-sulphonyl, piperidin-1-ylsulphonyl, homopiperidin-1-ylsulphonyl, morpholin-4-ylsulphonyl, homomorpholin-4-ylsulphonyl, piperazin-1-ylsulphonyl, 4-C1-3-alkyl-piperazin-1-ylsulphonyl, homopiperazin-1-ylsulphonyl or a 4-C1-3-alkyl-homopiperazin-1-ylsulphonyl group,
a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R6, where R6 denotes a 2-oxo-pyrrolidin-1-yl, 2-oxopiperidin-1-yl, 3-oxo-morpholin-4-yl, 2-oxo-imidazolidin-1-yl, 2-oxo-3-C1-3-alkyl-imidazoldin-1-yl, 2-oxo-hexahydropyrimidin-1-yl or a 2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl group,

- an azetidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a pyrrolidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-4-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined, or
- a tetrahydrofuran-3-yl, tetrahydropyran-3-yl or tetrahydropyran-4-yl group,

Rd denotes
a hydrogen atom or a fluorine, chlorine or bromine atom,
a hydroxy group,
a C1-4-alkyloxy group,
a methoxy group substituted by 1 to 3 fluorine atoms,
an ethyloxy group substituted by 1 to 5 fluorine atoms,
a C2-4-alkyloxy group which is substituted by a group R6 or R7, while
R6 is as hereinbefore defined and R7 denotes a hydroxy, C1-3-alkyloxy, C1-3-cycloalkyloxy, amino, C1-3-alkylamino, di-(C1-3-alkyl)amino, bis-(2-methoxyethyl)-amino, pyrrolidin-1-yl, piperidin-1-yl, homopiperidin-1-yl, morpholin-4-yl, homomorpholin-4-yl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-yl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-yl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-yl, piperazin-1-yl, 4-C1-3-alkyl-piperazin-1-yl, homopiperazin-1-yl or C1-3-alkyl-homopiperazin-1-yl group, or a formylamino, C1-3-alkylcarbonylamino, C1-3-alkyloxy-C1-3-alkyl-carbonylamino, C1-4-alkyloxycarbonylamino, aminocarbonylamino, C1-3-alkylaminocarbonylamino, di-(C1-3-alkyl)aminocarbonylamino pyrrolidin-1-ylcarbonylamino, piperidin-1-ylcarbonylamino, piperazin-1-ylcarbonylamino, 4-C1-3-alkyl-piperazin-1-ylcarbonylamino, morpholin-4-ylcarbonylamino or a C1-4-alkylsulphonylamino group,
a C3-7-cycloalkyloxy or C3-7-cycloalkyl-C1-4-alkyloxy group,
a tetrahydrofuran-3-yloxy, tetrahydropyran-3-yloxy or tetrahydropyran-4-yloxy group,
a tetrahydrofuranyl-C1-4-alkyloxy or tetrahydropyranyl-C1-4-alkyloxy group,
a C1-4-alkoxy group which is substituted by a pyrrolidinyl, piperidinyl or homopiperidinyl group substituted in the 1 position by the group R8, while
R8 denotes a hydrogen atom or a C1-3-alkyl group,

**or a C1-4-alkoxy group which is substituted by a morpholinyl group substituted in the 4 position by the group R8, while R8 is as hereinbefore defined, and**

**X denotes a nitrogen atom, and**

**by the aryl groups mentioned in the definition of the above groups is meant in each case a phenyl group which is mono- or disubstituted by R9, while the substituents may be identical or different and R9 denotes a hydrogen atom, a fluorine, chlorine, bromine or iodine atom or a C1-3-alkyl, hydroxy, C1-3-alkyloxy, difluoromethyl, trifluoromethyl, difluoromethoxy, trifluoromethoxy or cyano group,**

**by the heteroaryl groups mentioned in the definition of the above groups is meant a pyridyl, pyridazinyl, pyrimidinyl or pyrazinyl group, while said heteroaryl groups are each mono- or disubstituted by the group R9, while the substituents may be identical or different and R9 is as hereinbefore defined, and**

**said pyrrolidinyl, piperidinyl, piperazinyl and morpholinyl groups may be substituted in each case by one or two C1-3-alkyl groups, and**

**unless otherwise stated, said alkyl groups may be straight-chained or branched,**

**with the proviso that the compound 4-[(3-chloro-4-fluoro-phenyl)amino]-6((S)-tetrahydrofuran-3-yloxy)-7-hydroxy-quinazoline is excluded,**

**their tautomers, their stereoisomers, their mixtures and their salts.**

**Presently Pending AZ Claim 38 Compared to BI Claim 2 of the Interference (Overlap in Highlight)**

**2. A bicyclic heterocyclic compound of general formula I according to claim 1, wherein**

**$R^a$ denotes a hydrogen atom,**

**$R^b$ denotes a phenyl group substituted by the groups $R^1$ to $R^3$, while**

**$R^1$ denotes a hydrogen, fluorine, chlorine or bromine atom,**
**a methyl, trifluoromethyl or ethynyl group,**
**a phenyloxy or phenylmethoxy group, while the phenyl moiety of the abovementioned groups is optionally substituted by a fluorine or chlorine atom, or**
**a pyridyloxy or pyridinylmethoxy group, while the pyridinyl moiety of the abovementioned groups is optionally substituted by a methyl or trifluoromethyl group,**

**$R^2$ denotes a hydrogen, fluorine or chlorine atom or a methyl group and**

**$R^3$ denotes a hydrogen atom,**

**$R^c$ denotes a cyclopentyl group which is substituted in the 3 position by a group $R^4$-N-$R^5$, while**

**$R^4$ denotes a hydrogen atom or a $C_{1-3}$-alkyl group and**

**$R^5$ denotes a hydrogen atom or a $C_{1-3}$-alkyl group,**

**an aminocarbonyl-$C_{1-3}$-alkyl, $C_{1-3}$-alkylaminocarbonyl-$C_{1-3}$-alkyl, di-($C_{1-3}$-alkyl)aminocarbonyl-$C_{1-3}$-alkyl, pyrrolidin-1-ylcarbonyl-$C_{1-3}$-alkyl, piperidin-1-ylcarbonyl-$C_{1-3}$-alkyl, piperazin-1-ylcarbonyl-$C_{1-3}$-alkyl, 4-$C_{1-3}$-alkyl-piperazin-1-yl-carbonyl-$C_{1-3}$-alkyl or morpholin-4-ylcarbonyl-$C_{1-3}$-alkyl group,**

**a hydroxy-$C_{2-4}$-alkyl, $C_{1-3}$-alkyloxy-$C_{2-4}$-alkyl, $C_{1-4}$-alkyloxy-carbonylamino-$C_{2-4}$-alkyl, amino-$C_{2-4}$-alkyl, $C_{1-3}$-alkylamino-$C_{2-4}$-alkyl, di-($C_{1-3}$-alkyl)amino-$C_{2-4}$-alkyl, $C_{1-3}$-alkylcarbonylamino-$C_{2-4}$-alkyl, aminocarbonylamino-$C_{2-4}$-alkyl, $C_{1-3}$-alkylaminocarbonylamino-$C_{2-4}$-alkyl, di-($C_{1-3}$-alkyl)amino-carbonylamino-$C_{2-4}$-alkyl, morpholin-4-ylcarbonylamino-$C_{2-4}$-alkyl, $C_{1-3}$-alkylsulphonyl-$C_{2-4}$-alkyl or $C_{1-3}$-alkylsulphonylamino-$C_{2-4}$-alkyl group,**

a (2-oxo-pyrrolidin-1-yl)-$C_{2-4}$-alkyl, (2-oxopiperidin-1-yl)-$C_{2-4}$-alkyl, (3-oxo-morpholin-4-yl)-$C_{2-4}$-alkyl, (2-oxo-imidazolidin-1-yl)-$C_{2-4}$-alkyl, (2-oxo-3-methyl-imidazolidin-1-yl)-$C_{2-4}$-alkyl, (2-oxo-hexahydropyrimidin-1-yl)-$C_{2-4}$-alkyl or (2-oxo-3-methyl-hexahydropyrimidin-1-yl)-$C_{2-4}$-alkyl group,

a $C_{1-3}$-alkylsulphonyl, chloro-$C_{2-4}$-alkylsulphonyl, bromo-$C_{2-4}$-alkylsulphonyl, amino-$C_{2-4}$-alkylsulphonyl, $C_{1-3}$-alkylamino-$C_{2-4}$-alkylsulphonyl, di-($C_{1-3}$-alkyl)amino-$C_{2-4}$-alkylsulphonyl, (pyrrolidin-1-yl)-$C_{2-4}$-alkylsulphonyl, (piperidin-1-yl)-$C_{2-4}$-alkylsulphonyl or (morpholin-4-yl)-$C_{2-4}$-alkylsulphonyl group,

a $C_{1-4}$-alkyloxy-carbonyl group,

a formyl, $C_{1-3}$-alkyl-carbonyl, $C_{1-3}$-alkyloxy-$C_{1-3}$-alkyl-carbonyl, tetrahydrofuranylcarbonyl, tetrahydropyranylcarbonyl, amino-$C_{1-3}$-alkyl-carbonyl, $C_{1-3}$-alkylamino-$C_{1-3}$-alkyl-carbonyl, di-($C_{1-3}$-alkyl)amino-$C_{1-3}$-alkyl-carbonyl, pyrrolidin-1-yl-$C_{1-3}$-alkyl-carbonyl, piperidin-1-yl-$C_{1-3}$-alkyl-carbonyl, piperazin-1-yl-$C_{1-3}$-alkyl-carbonyl, 4-$C_{1-3}$-alkyl-piperazin-1-yl-$C_{1-3}$-alkyl-carbonyl, morpholin-4-yl-$C_{1-3}$-alkyl-carbonyl or a $C_{1-3}$-alkylsulphonyl-$C_{1-3}$-alkyl-carbonyl group,

a cyano, aminocarbonyl, $C_{1-3}$-alkyl-aminocarbonyl, di-($C_{1-3}$-alkyl)aminocarbonyl, ($C_{1-3}$-alkyloxy-$C_{2-4}$-alkyl)aminocarbonyl, N-($C_{1-3}$-alkyl)-N-($C_{1-3}$-alkyloxy-$C_{2-4}$-alkyl)aminocarbonyl, phenylaminocarbonyl, pyrrolidin-1-ylcarbonyl, piperidin-1-ylcarbonyl, morpholin-4-ylcarbonyl, $C_{1-3}$-alkyl-morpholin4-ylcarbonyl, di-($C_{1-3}$-alkyl)morpholin-4-ylcarbonyl, homomorpholin-4-ylcarbonyl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-ylcarbonyl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-ylcarbonyl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-ylcarbonyl, piperazin-1-ylcarbonyl, 4-($C_{1-3}$-alkyl)-piperazin-1-ylcarbonyl, aminosulphonyl, $C_{1-3}$-alkyl-aminosulphonyl, di-($C_{1-3}$-alkyl)amino-sulphonyl, pyrrolidin-1-yl-sulphonyl, piperidin-1-ylsulphonyl or a morpholin-4-ylsulphonyl group, or

a cyclopentyl group which is substituted in the 3 position by a group $R^6$, while

$R^6$ denotes a 2-oxo-pyrrolidin-1-yl, 2-oxopiperidin-1-yl, 3-oxo-morpholin-4-yl, 2-oxo-imidazolidin-1-yl, 2-oxo-3-methyl-imidazolidin-1-yl, 2-oxo-hexahydropyrimidin-1-yl or a 2-oxo-3-methyl-hexahydropyrimidin-1-yl group,

a cyclohexyl group which is substituted in the 3 position or in the 4 position by a group $R^4$-N-$R^5$, while $R^4$ and $R^5$ are as hereinbefore defined,

a cyclohexyl group which is substituted in the 3 position or in the 4 position by a group $R^6$, while $R^6$ is as hereinbefore defined,

a pyrrolidin-3-yl group which is substituted in the 1 position by the group $R^5$, while $R^5$ is as hereinbefore defined,

a piperidin-3-yl group which is substituted in the 1 position by the group $R^5$, while $R^5$ is as hereinbefore defined,

a piperidin-4-yl group which is substituted in the 1 position by the group $R^5$, while $R^5$ is as hereinbefore defined, or

a tetrahydrofuran-3-yl, tetrahydropyran-3-yl or tetrahydropyran-4-yl group,

$R^d$ denotes a hydrogen atom,

a $C_{1-3}$-alkyloxy group,

a methoxy group which is substituted by one to three fluorine atoms,
an ethyloxy group which is substituted in the 2 position by a group $R^6$ or $R^7$, while $R^6$ is as hereinbefore defined and

$R^7$ denotes a hydroxy, $C_{1-3}$-alkyloxy, amino, $C_{1-3}$-alkylamino, di-($C_{1-3}$-alkyl)amino, bis-(2-methoxyethyl)-amino pyrrolidin-1-yl, piperidin-1-yl, morpholin-4-yl, homomorpholin-4-yl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-yl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-yl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-yl, piperazin-1-yl or a 4-$C_{1-3}$-alkyl-piperazin-1-yl group, or

a formylamino, $C_{1-4}$-alkylcarbonylamino, $C_{1-3}$-alkyloxy-$C_{1-3}$-alkyl-carbonylamino, $C_{1-4}$-alkyloxycarbonylamino, aminocarbonylamino, $C_{1-3}$-alkylaminocarbonylamino, di-($C_{1-3}$-alkyl)aminocarbonylamino, pyrrolidin-1-ylcarbonylamino, piperidin-1-ylcarbonylamino, piperazin-1-ylcarbonylamino, 4-$C_{1-3}$-alkyl-piperazin-1-ylcarbonylamino- morpholin-4-ylcarbonylamino or a $C_{1-4}$-alkylsulphonylamino group,

a propyloxy group which is substituted in the 3 position by a group $R^6$ or $R^7$, while $R^6$ and $R^7$ are as hereinbefore defined, or

a butyloxy group which is substituted in the 4 position by a group $R^6$ or $R^7$, while $R^6$ and $R^7$ are as hereinbefore defined, and

X denotes a nitrogen atom,

while, unless stated otherwise, said alkyl groups may be straight-chained or branched,

their tautomers, their stereoisomers, their mixtures and their salts.

And as above, It can be seen that compared to BI interference claims 1 and 2, claim 38, reading as follows, is even more narrow than indicated in the above highlighting:

> A compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(N-methylcarbamoylmethyl)piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts.

As can be seen, in BI claim 1, $R^a$ may be five different groups, in BI claim 2, $R^a$ is hydrogen. In present claim 38, $R^a$ must be hydrogen. In BI claim 1, while $R^b$ may be only two different groups, it is substituted by 0, 1, 2, or 3 substituents. And, the substituents on $R^b$, $R^1$and $R^2$, can be independently chosen from 11 different groups and 12 classes of compounds, while another substituent on $R^b$, $R^3$, can be chosen from 6 different groups. In BI claim 2, $R^b$ is a phenyl group substituted by $R^1$to $R^3$; $R^1$ may be chosen from 11 groups, some optionally substituted, $R^2$ may be chosen from 4 groups, and $R^3$ is a hydrogen atom. In present claim 38, $R^b$ must be phenyl substituted at the 3-position with chloro and at the 2-position with fluoro. In other words, there are only two substituents and the ring position of each is specifically recited in the present claims. That is not the case in BI's claims 1 and 2.

In addition, in BI claims 1 and 2, $R^c$ may be chosen from 10 different groups, whereas in claim 38, it is piperidin-4-yl. And each $R^c$may be substituted by a substituent chosen from long lists. However, in present claim 38 that substituent at the $R^c$ position is N-methylcarbamoylmethyl.

Finally, in BI claim 1, $R^d$ may be chosen from 10 different groups and 8 different classes of groups that may be substituted, while in BI claim 2, $R^d$ may be chosen from 5

different groups which can be substituted and one class of groups. In present claim 38, the corresponding group is limited to methoxy.

Compared to AZ claim 23, it is clear that BI claims 1 and 2 contain even more species and thus cover numbers into the millions of compounds. Nothing in the lost counts of the interference directs one skilled in the art, among those millions, to the species and its salts recited in claim 38.

Accordingly, due to the breadth of the lost count BI claims 1 and 2, and the lack of any suggestion to select the presently claimed species, claim 38 is patentably distinct over both BI claims 1 and 2, as supported by M.P.E.P. § 2144.08, *Takeda,* and *Baird*.

Applicants' representatives also explained that lost BI claims 3-5 are drawn to 3- or 3,4- substitution on the phenyl ring and lost BI claim 6 is drawn solely to 3,4-substitution on the phenyl ring. In contrast, as discussed above, the present claims 38-43 all recite 2-fluoro, 3-chloro substitution on the phenyl ring. Accordingly, BI claims 3-5 teach away from the 2,3-ring positions recited in claims 38-43, as amended, just as was the case in *Baird*. Applicants' representatives thus expressed their belief at the interview that claims 38-43, which are drawn to a species having fluoro and chloro in specific 2,3-ring positions, are patentably distinct over lost BI claims 3-6.

Applicants' representatives may have misunderstood, but the Office may have suggested at the interview that another basis for interference estoppel is Example 11 of the Bradbury AZ application in interference. To the extent the Office took that position, the position is simply wrong and in an abundance of caution, is addressed herein.

As explained above, Bradbury, including its disclosed Example 11, is not prior art under § 103(c). Moreover, the lost counts of the interference do not specifically recite

the subject matter of Example 11. And as will be explained now, such a claim directed to Example 11 could not have been presented in the interference because Example 11 is not clearly common subject matter in Bradbury and the BI disclosure.

**1. No Procedural Bar to Seeking Present Claims**

Applicants are not procedurally barred from seeking relief that could have been, but was not, sought in the interference. In the present case, relief could not have been sought in the interference for the pending claims.

For example, as clearly exemplified in the Federal Register's Notice of Proposed Rulemaking, 49 FR 3768, dated January 30, 1984 (relevant portion attached), if one party to the interference could not have properly moved to add a count to a species because that species was not disclosed in the other party's application, that one party whose application does encompass the species is not estopped after losing the interference from seeking a patent to obtain a patent containing claims to the species.

More specifically, at page 20, Example 31, the Federal Register exemplifies a situation where one applicant (referred to herein as "Applicant A", but referred to as "Applicant AU" in the Register) discloses a generic invention to "solvent" as well as species thereof, including benzene and toluene. The only claim in Applicant A's application is claim 1, drawn to a "solvent".

An interference between Applicant A and another applicant (referred to herein as "Applicant B", but referred to as "Applicant AT" in the Register) is declared with a single count drawn to a "solvent". However, Application B also discloses benzene. Claim 1 of Application A and claim 3 of Application B are designated as corresponding to the

count. No preliminary motions are filed. A judgment is entered in favor of Applicant B on the sole count directed to solvent.

Losing Applicant A would be estopped to obtain a patent containing a claim to benzene, because they failed to file a preliminary motion seeking to add a count to that species. Applicant A could have done that because Applicant B also disclosed benzene and thus both parties A and B had benzene as subject matter clearly common to both applications. However, Applicant A would not be estopped to obtain a patent containing claims to toluene, because Applicant A could not have properly moved to add a count to toluene, since toluene was not disclosed by Applicant B.[6] In other words, toluene was not subject matter clearly common to both applications.

Although the Federal Register's example was published before the new Interference Rules became effective on September 13, 2004, and Federal Register statements are not binding on the Office (*Tafas v. Doll*, slip op. at 17, n 5 (Fed. Cir., March 20, 2009) (copy attached), the new rules did not change that time-honored explication of interference estoppel set forth in the 1984 rules. For example, see current 35 U.S.C. § 135 at Interpretive Notes and Decisions, No. 198 (emphasis added) ("Claim in application of party losing interference proceeding cannot be rejected on ground of interference estoppel ***except*** relative to ***subject matter clearly common to applications of both parties***...." *In re Wilding,* 535 F.2d 631 (1976, CCPA)). *See also In re Wilding,* 535 F.2d 631 (1976, CCPA).

[6] Applicant A would have to establish that toluene is a separately patentable invention from solvent. Above, we have explained that claims 38-43 are separately patentable from the lost count of the interference.

Nothing has been found inconsistent with that 1984 Register principle either in the Federal Register after the 1984 rules were enacted or in the case law. And *Wilding* has never been overrruled or questioned on that point. Accordingly, there can be no interference estoppel when the subject matter is **not** clearly common to applications of **both** parties.

In the present case, BI's patents do not have the necessary written description support under 35 U.S.C. § 112 to present either the subject matter of pending claims 38-43, as amended, or Example 11. Neither of BI's patents even remotely conveys to one of ordinary skill in the art that, as of their filing dates, the inventors had possession of the species and salts thereof presently claimed, as amended, or the species disclosed in Bradbury Example 11. All of BI's 186 exemplified species are either 3- or 3,4- substituted. None is 2,3-substituted as required by the present claims and as recited in Example 11.

Accordingly, the presently claimed subject matter was not common to the applications of both parties to the interference, and AZ could not have properly moved to add a count to the subject matter of claims 38-43, as amended or to the subject matter of Example 11. Simply put, the subject matter of claims 38-43, as amended, and the subject matter of Example 11 were not clearly common to the disclosure of the BI patent.

Hence, regarding claims 38-43, as amended, and Example 11, no interference estoppel can be found against the Applicants. And thus, Example 11, not otherwise being prior art, cannot constitute any form of interference estoppel against claims 38-43, as amended.

**B. No Obviousness-Type Double Patenting**

As mentioned above, during the interview, the issue of obviousness-type double patenting of the pending claims in view of the pending claims in Bradbury Application No. 12/147,250 (the currently-pending continuation of the U.S. national phase application of WO 03/082831) and Example 11 thereof was raised. Applicants disagreed that there is an issue of obviousness-type double patenting. Applicants will now explain in detail the bases for their disagreement.

Any such double patenting issue would be provisional at this point since neither Application No. 12/147,250 nor the present application yet has an indication of allowable subject matter. However, solely to expedite prosecution, Applicants will pre-emptively explain why an obviousness-type double patenting rejection would be improper and should not be made.

To be sure, claim 38 falls within the literal scope of claim 24 of Application No. 12/147,250. But that fact alone does not establish obviousness-type double patenting of claim 38. With respect to such a situation, the M.P.E.P. cautions:

> **Domination and double patenting should not be confused.** They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. **Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.**

M.P.E.P. § 804(II) (*citing In re Kaplan,* 789 F.2d 1574, 1577-78 (Fed. Cir. 1986); and *In re Sarrett*, 327 F.2d 1005, (CCPA 1964)) (emphasis added).

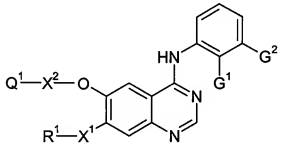
Hence, it is not enough that claim 24 encompasses the subject matter of claims 38-43, as amended. Rather, to support an obviousness-type double patenting rejection,

claims 24-35 of Application No. 12/147,250 must have rendered obvious the present claims 38-43, as amended.

Claims 24-35 are pending in Application No. 12/147,250. As shown below, present claim 38 is patentably distinct over the claims of that copending application due to the breadth of the copending claims, and, as in *Baird*, the total lack of suggestion in the lost count to select the presently claimed compound/salts recited in present claims 38-43, as amended.

**Copending Claims 24-35 With Present Claim 38 Overlap Highlighted**

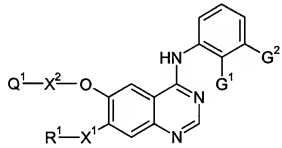
**24. A quinazoline of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is halogeno;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is heterocyclyl, wherein $Q^1$ optionally bears 1 or 2 substituents, which may be the same or different, selected from carbamoyl, (1-6C)alkyl, (1-6C)alkylsulphonyl, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, (2-6C)alkanoyl, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, and N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;**
**or a pharmaceutically acceptable salt thereof.**

**25. A quinazoline according to claim 24, wherein $Q^1$ is heterocyclyl, optionally bearing 1 or 2 substituents, which may be the same or different, selected from carbamoyl, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, and N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from $NR^aR^b$, wherein $R^a$ is hydrogen and $R^b$ is hydrogen; or a pharmaceutically acceptable salt thereof.**

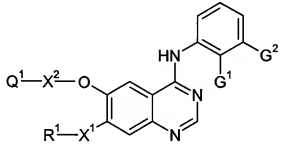
**26. At least one compound chosen from (a) quinazolines of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is halogeno;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is heterocyclyl, wherein $Q^1$ optionally bears 1 or 2 substituents, which may be the same or different, selected from carbamoyl, (1-6C)alkyl, (1-6C)alkylsulphonyl, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, (2-6C)alkanoyl, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, and N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;**
**and (b) pharmaceutically acceptable salts thereof.**

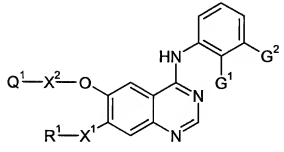
**27. At least one compound according to claim 26, wherein in said quinazolines (a),**
**$Q^1$ is heterocyclyl, optionally bearing 1 or 2 substituents, which may be the same or different, selected from carbamoyl, (1-6C)alkyl, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]-carbamoyl, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, and N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl,**
**and wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from $NR^aR^b$, wherein $R^a$ is hydrogen and $R^b$ is hydrogen;**
**and (b) pharmaceutically acceptable salts thereof.**

**28. A quinazoline of Formula I:**



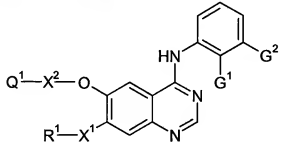

**wherein:**
**$G^1$ and $G^2$ each independently is chosen from fluoro and chloro;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is linked to $X^2$ -O by a ring carbon atom and is a heterocyclyl chosen from pyrrolidin-3-yl, pyrrolidin-2-yl, 3-pyrrolin-3yl, piperidin-4-yl, piperidin-3yl, piperidin-2yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, piperazin-3-yl, and 1,2,3,6-tetrahydropyridin-4-yl, wherein $Q^1$ bears 1 or 2 substituents selected from N-(1-6C)alkylcarbamoyl and N-(1-6C)alkylcarbamoyl(1-6C)alkyl,**
**or a pharmaceutically acceptable salt thereof.**

**29. At least one compound chosen from (a) quinazolines of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is chosen from fluoro and chloro;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is linked to $X^2$-O by a ring carbon atom and is a heterocyclyl chosen from pyrrolidin-3-yl, pyrrolidin-2-yl, 3-pyrrolin-3yl, piperidin-4-yl, piperidin-3yl, piperidin-2yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, piperazin-3-yl, and 1,2,3,6-tetrahydropyridin-4-yl, wherein $Q^1$ bears 1 or 2 substituents selected from: N-(1-6C)alkylcarbamoyl, (1-6C)alkyl, and N-(1-6C)alkylcarbamoyl(1-6C)alkyl, and (b) pharmaceutically acceptable salts thereof.**

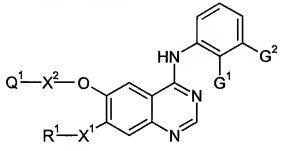
**30. A quinazoline of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is halogeno;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is a non-aromatic saturated 5 or 6 membered monocyclic heterocyclyl ring with at least one nitrogen atom, which ring is linked to the group $X^2$-O- by a carbon atom in the ring,**

**wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;**
**or a pharmaceutically acceptable salt thereof.**

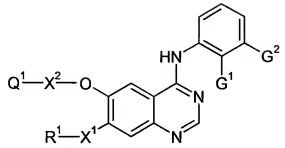
**31. A quinazoline of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is halogeno;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is a non-aromatic saturated 4, 5 or 6 membered monocyclic heterocyclyl ring with 1 or 2 ring nitrogen heteroatom(s), which ring is linked to the group $X^2$-O- by a ring carbon atom,**
**wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;**
**or a pharmaceutically acceptable salt thereof.**

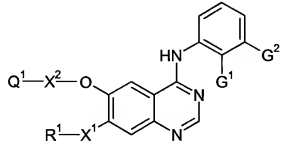
**32. The quinazoline of Formula I according to claim 31, wherein in said quinazolines (a),**
**$Q^1$ is selected from pyrrolidin-3-yl, pyrrolidin-2-yl, piperidin-4-yl, piperidin-3-yl, piperidin-2-yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, and piperazin-3-yl**
**and (b) pharmaceutically acceptable salts thereof.**

**33. A quinazoline of Formula I:**




**wherein:**
**$G^1$ is fluoro and $G^2$ is chloro;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is linked to $X^2$ -O by a ring carbon atom and is a heterocyclyl chosen from pyrrolidin-3-yl, pyrrolidin-2-yl, 3-pyrrolin-3yl, piperidin-4-yl, piperidin-3-yl, piperidin-2yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, piperazin-3-yl, and 1,2,3,6-tetrahydropyridin-4-yl, and**
**wherein $Q^1$ bears 1 or 2 substituents selected from N-(1-6C)alkylcarbamoyl and N-(1-6C)alkylcarbamoyl(1-6C)alkyl,**
**or a pharmaceutically acceptable salt thereof.**

**34. A quinazoline of Formula I:**

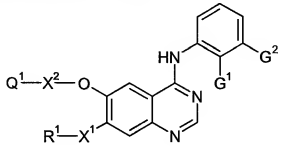



**wherein:**
**$G^1$ and $G^2$ each independently is chosen from fluoro and chloro;**
**$X^1$-$R^1$ is methoxy;**
**$X^2$ is a direct bond;**
**$Q^1$ is linked to $X^2$ -O by a ring carbon atom and is a heterocyclyl chosen from pyrrolidin-3-yl, pyrrolidin-2-yl, 3-pyrrolin-3yl, piperidin-**

**4-yl, piperidin-3yl, piperidin-2yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, piperazin-3-yl, and 1,2,3,6-tetrahydropyridin-4-yl, and**

**wherein $Q^1$ bears 1 or 2 substituents selected from N-(1-6C)alkylcarbamoyl and N-(1-6C)alkylcarbamoyl(1-6C)alkyl, or a pharmaceutically acceptable salt thereof.**

**35. A quinazoline of Formula I:**




**wherein:**
**$G^1$ and $G^2$ each independently is chosen from fluoro and chloro;**
**$X^1$ is O;**
**$R^1$ is (1-4C)alkyl;**
**$X^2$ is a direct bond;**
**$Q^1$ is linked to $X^2$ -O by a ring carbon atom and is a heterocyclyl chosen from pyrrolidin-3-yl, pyrrolidin-2-yl, 3-pyrrolin-3yl, piperidin-4-yl, piperidin-3yl, piperidin-2yl, homopiperidin-3-yl, homopiperidin-4-yl, piperazin-2-yl, piperazin-3-yl, and 1,2,3,6-tetrahydropyridin-4-yl, and**

**wherein $Q^1$ bears 1 or 2 substituents selected from N-(1-6C)alkylcarbamoyl and N-(1-6C)alkylcarbamoyl(1-6C)alkyl, or a pharmaceutically acceptable salt thereof.**

As can be seen, claim 33 of the copending Application No. 12/147,250 is the only claim wherein $G^1$ is limited to fluoro and $G^2$ is limited to chloro, as in the present claims 38-43, as amended. In claim 33 of the copending Application No. 12/147,250, $Q^1$ may be any of 11 different groups. In contrast, $Q^1$ in present claim 38 is the single heterocyclyl, piperidin-4-yl. In claim 33 of the copending Application No. 12/147,250, $Q^1$ may be mono- or di-substituted with substituent(s) chosen from 2 classes of groups comprising 42 different groups (the class of N-(1-6C)alkylcarbamoyl groups comprises 6

groups and the class of N-(1-6C)alkylcarbamoyl(1-6C)alkyl groups comprises 36 different groups).

However, in present claim 38, $Q^1$ bears the single substituent N-methyl-carbamoylmethyl. There are many hundreds of thousands, if not millions of possibilities in claim 33 of the continuation.[7] And nothing in any of the copending claims 24-35 in any way suggests or directs toward the species and its salts recited in claim 38.

Accordingly, due to the breadth of claim 33 and the lack of any guideposts or blaze marks in claim 33, or any other claim, of the copending application leading to the narrower, present claim 38, claim 38 is not rendered obvious by claim 33.

For the same reasons, claims 24-32, 34, and 35 also would have failed to render the present claims 38-43, as amended, obvious.

Applicants' also believe that the present claims 39-43 are no broader in compound or salt scope than present claim 38 and thus claims 39-43 are not obvious in view of claims 24-35 of Application No. 12/147,250 for the same reasons that claim 38 is not obvious in view of claim 33 of the copending application.

---

[7] There are many hundreds of thousands, if not millions, of compounds encompassed by claim 33 of the AZ continuation application, estimated as folllows:
$R^1$ may (1-4C)alkyl, thus there are seven possible compounds including branched alkyls.
$Q^1$ may be chosen from 11 different groups. Thus, 77 (11 times 7) compounds are possible. Furthermore, $Q^1$ may be substituted by 1 or 2 substituents selected from N-(1-6C)alkylcarbamoyl and N-(1-6C)alkylcarbamoyl(1-6C)alkyl. Thus, $Q^1$ may be substituted by 1 or 2 substituents selected from 42 substituents. Taking 77 compounds, as discussed above, and multiplying by the number of possible single substituents (42) means 3,234 compounds would be encompassed by claim 33. Taking 77 compounds, as discussed above, and multiplying by the number of possible double substituents (42 squared = 1764) means 135,828 compounds plus the 3,234 compounds if $Q^1$ were singly-substituted means that claim 33 would encompass 139,062 compounds. And there are numerous pharmaceutically acceptable salts of those compounds disclosed. *See,e.g.,* p. 19, lines 5-12 of PCT parent published as WO 2003/082831 and para. [0062] US Published Application No. 2008/0269487 (the US publication of the AZ continuation).

As mentioned above, at the interview, the Office raised Example 11 of Application No. 12/147,250 as a basis for obviousness type double patenting. There are very limited circumstances in which specification disclosure can be relevant in obviousness-type double patenting, and neither circumstance is present to render Example 11 relevant in this obviousness-type double patenting situation.

As set forth in M.P.E.P. § 804, the specification **can** be used as a dictionary to learn the meaning of a term in the patent claim. But there is no need to look at Example 11 to understand any term in claims 24-35 of Application No. 12/147,250.

Furthermore, according to M.P.E.P. § 804, portions of the specification which provide support for the patent claims **can** be examined and considered. But Example 11 is a non-issue with respect to support for claims 24-35 of Application No. 12/147,250 because there is adequate support for those claims apart from Example 11. See *In re Kaplan, supra,* at 1580.

In the copending Application No. 12/147,250, there is support for $G^1$ and $G^2$ each independently being halogeno, as recited in claims 24-27 and 30-32 at, for example, page 5, line 30.[8] There is also support for $G^1$ and $G^2$ each independently being chosen from fluoro and chloro, as recited in copending claims 28, 29, 34, and 35, at, for example, page 25, line 26, and support for $G^1$ being fluoro and $G^2$ being chloro at page 25, line 27.

$X^1$ is O in all of the copending claims of Application No. 12/147,250. Support for that limitation can be found, for example, at page 5, line 31.

[8] Cites for supporting disclosure are from the parent PCT publication, WO 03/082,831.

$R^1$ is (1-4C)alkyl in copending claims 24-33 and 35, which is supported by, for example, page 25, line 23, of the copending Application No. 12/147,250. In claim 34, $X^1$-$R^1$ is methoxy. That limitation is supported, for example, at page 25, line 25, of the copending Application No. 12/147,250.

Support for the various claimed $Q^1$ groups and substituents for each of copending claims 24-35 can be found, for example, at page 6, line 13- page 7, line 18, page 12, lines 20-24, page 25, line 28 to at least page 50, line 17 of copending Application No. 12/147,250.

Accordingly, Example 11 is irrelevant for obviousness-type double patenting, as further supported by M.P.E.P. § 804. That section also addresses the issue of use of the specification disclosure to determine, in the absence of the two limited circumstances recited above, issues of double patenting.

As here, absent those limited circumstances, M.P.E.P. § 804 clearly states: "[w]hen considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, **the disclosure of the patent may not be used as prior art.**" M.P.E.P. § 804 (internal citations omitted) (emphasis added).

As noted above, the limited circumstances described in M.P.E.P. § 804 do not exist in the present application. In view of the lack of those circumstances, Example 11 simply cannot be considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the copending application.

That conclusion of M.P.E.P. § 804 and its relevance to the instant application find support in the case law. In *In re Kaplan, supra* (cited with approval in the M.P.E.P. and a copy of which is submitted herewith), an application claimed an improvement in a process of making certain alkane diols and triols by reacting certain reagents in the presence of a "solvent mixture of tetraglyme and sulfolane." The PTO rejected the claims on grounds of obviousness-type double patenting in view of a prior 102(e) patent that claimed "an organic solvent". The Board held that appellants had eliminated the prior patent as prior art. However, the Board made an obviousness-type double patenting rejection in view of one Example in the prior patent, which exemplified the use of a solvent mixture of tetraglyme and sulfolane.

Thus, the Board used that Example in the prior patent against the appellants even though they had eliminated the patent as prior art, just as Applicants have herein eliminated Bradbury. Specifically, the Board in *Kaplan* argued that the Example at issue "provides some of the support for the term 'organic solvent'" as used in a claim in the prior patent and, thus, could be considered for purposes of an obviousness-type double patenting rejection. *Kaplan,* 789 F.2d at 1580.

However, the Federal Circuit disagreed, and held that the Board had improperly used the Example as prior art in making its double patenting rejection. Specifically, the Court made clear that once it is established that there is adequate support in other parts of the disclosure for claims at issue, a specific slice of disclosure, such as Bradbury's Example 11, cannot be used for double patenting purposes:

> The board's claim-support theory does not suffice to justify this anomalous result. There is ***adequate support for the "organic solvent" limitation in claim 4 [of the prior patent] apart from*** appellants' specific *mixed* solvent invention, including the disclosure of

> the separate solvents in the mixture which are separately claimed by Kaplan. **There is no way the board could have found appellants' claimed invention to be an obvious variation of what Kaplan claims except by treating the [Example] as though it were prior art. This has repeatedly been held in our precedents to be impermissible.**

*In re Kaplan*, 789 F.2d at 1580 (internal citations omitted) (emphasis added).

In other words, the Federal Circuit held that, where there is adequate support elsewhere in the specification for a claimed term, an Example in a prior patent cannot be used as a basis for an obviousness-type double patenting rejection. The Office here would be repeating the same error made by the Board in *Kaplan* if it were to make a double patenting rejection utilizing Example 11 of Bradbury.

For the foregoing reasons, Applicants assert that an obviousness-type double patenting of the pending claims in view of the pending claims and/or Example 11 Application No. 12/147,250 would be improper. Rather, the Office should allow claims 38-43, as amended.

## V. Conclusion

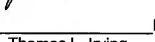
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

**Jill MacAlpine, Reg. No. 60, 475**



Dated: April 6, 2009

By:_____**FOR**
Thomas L. Irving
Reg. No. 28,619
(202) 408-4082

**Attachments:**

Exhibit A

1) *In re Hilmer*, 359 F.2d 859, 149 USPQ 480 (CCPA 1966)
2) *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992);
3) *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985).
4) 37 CFR § 41.127(a)(1)
5) *Ex parte Kimura*, 55 USPQ2d 1537 (Bd. Pat. App. & Inter. 2000)
6) *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990)
7) *Net MoneyIN, Inc. v. Verisign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008)
8) *Eisai Co. Ltd. v. Teva Pharmaceuticals USA, Inc.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008)
9) *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)
10) *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992)
11) *Takeda Chemical Industries, Ltd. V. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356; (Fed. Cir. 2007)
12) *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995)
13) Pages from Federal Register's Notice of Proposed Rulemaking, 49 FR 3768, dated January 30, 1984
14) *Tafas v. Doll*, slip op. (Fed. Cir. March 20, 2009)
15) *In re Wilding*, 535 F.2d 631 (1976, CCPA)
16) *In re Kaplan*, 789 F.2d 1574, 1577-78 (Fed. Cir. 1986)
17) *In re Sarrett*, 327 F.2d 1005, (CCPA 1964)

# Exhibit A

# U.S. Application No. 10/571,991
# Interview March 5, 2009

# U.S. Application No. 10/571,991

**Claims: Claims 38-71 are pending**

- **Claims 44-71 are withdrawn from consideration**
- **Claims 38-43 are rejected**

**Status: Final Office Action mailed 01/06/2009**

- **§ 103(a) rejection over WO 03/082831 ("Bradbury")**

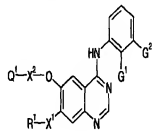
# NO INTERFERENCE ESTOPPEL

**All continuation claims are patentably distinct from the lost interference counts and all claims (lost claims) corresponding to those counts**

# '991 Claim 38 is Patentably Distinct Over Lost AZ Interference Claim 23 (Alternative Part of the Lost Count)

# SUBSTITUENTS IN BLACK ARE IN LOST INTERFERENCE AZ CLAIM 23 (ALTERNATIVE PART OF LOST COUNT) BUT NOT IN NARROWER CLAIM 38

Claim 23. A quinazoline derivative of the Formula I:



wherein:

$G^1$ and $G^2$ each independently is halogeno;

$X^1$ is a direct bond or O;

$R^1$ is (1-6C)alkyl, wherein the (1-6C)alkyl group is optionally substituted by one or more substituents, which may be the same or different, selected from hydroxy, and/or a substituent selected from amino, (1-6C)alkoxy, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, (2-6C)alkanoylamino, and (1-6C)alkanesulphonylamino;

$X^2$ is a direct bond;

$Q^1$ is (3-7C)cycloalkyl or heterocyclyl, wherein $Q^1$ optionally bears 1, 2, or 3 substituents, which may be the same or different, selected from cyano, amino, carbamoyl, (1-6C)alkyl, (1-6C)alkylsulphonyl, (1-6C)alkylamino, di-[(1-6C)alkyl]amino, N-(1-6C)alkylcarbamoyl, N,N-di-[(1-6C)alkyl]carbamoyl, (2-6C)alkanoyl, (2-6C)alkanoylamino, N-(1-6C)alkyl(2-6C)alkanoylamino, sulphamoyl, N-(1-6C)alkylsulphamoyl, N,N-di[(1-6C)alkyl]sulphamoyl, (1-6C)alkanesulfonylamino, N-(1-6C)alkyl-(1-6C)alkanesulfonylamino, carbamoyl(1-6C)alkyl, N-(1-6C)alkylcarbamoyl(1-6C)alkyl, N,N-di-[(1-6C)alkyl]carbamoyl(1-6C)alkyl, and (2-6C)alkanoylamino(1-6C)alkyl, and

wherein any (1-6C)alkyl and (2-6C)alkanoyl group within $Q^1$ optionally bears one or more substituents, which may be the same or different, selected from halogeno and hydroxy, and/or optionally a substituent selected from (1-6C)alkoxy and $NR^aR^b$, wherein $R^a$ is hydrogen or (1-4C)alkyl and $R^b$ is hydrogen or (1-4C)alkyl, or $R^a$ and $R^b$ together with the nitrogen atom to which they are attached form a 5 or 6 membered ring, which optionally bears 1 or 2 substituents on an available ring carbon atom selected from (1-4C)alkyl;

and wherein any heterocyclyl group within the $Q^1$-$X^2$- group optionally bears 1 oxo (=O) substituent;

or a pharmaceutically acceptable salt thereof.

## '991 Claim 38 is Patentably Distinct Over Lost Interference AZ Claims 24 and 25

**Lost AZ Interference Claim 24 (composition claim) and Lost AZ Interference Claim 25 (method claim) are of the same scope as Lost AZ Interference Claim 23 with respect to the compound or salt**

**Therefore '991 claim 38 is patentably distinct over Lost AZ Interference Claims 24 and 25 for the same reasons it is patentably distinct over Lost AZ Interference Claim 23**

## '991 Claims 39-43 are Patentably Distinct Over Lost AZ Interference Claims 23-25

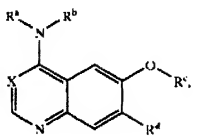
**'991 Claims 39-43 are no broader in compound or salt scope than '991 Claim 38**

**Those claims are patentably distinct for the same reasons that '991 Claim 38 is patentably distinct over Lost AZ Interference Claims 23-25**

# '991 Claim 38 is Patentably Distinct From Lost BI Claim 1, Alternative Part of the Lost Count

# SUBSTITUENTS IN BLACK ARE IN LOST BI INTERFERENCE CLAIM 1 (ALTERNATIVE PART OF LOST COUNT) BUT NOT IN '991 CLAIM 38

**1. A compound of the general formula**



(I)

**wherein**

**$R^a$ denotes a hydrogen atom or a C1-4-alkyl group,**

**$R^b$ denotes a phenyl or 1-phenylethyl group, wherein the phenyl nucleus is substituted in each case by the groups $R^1$ to $R^3$, while**

**$R^1$ and $R^2$, which may be identical or different, in each case denote a hydrogen, fluorine, chlorine, bromine or iodine atom, a C1-4-alkyl, hydroxy, C1-4-alkoxy, C2-3-alkenyl or C2-3-alkynyl group, an aryl, aryloxy, arylmethyl or arylmethoxy group, a heteroaryl, heteroaryloxy, heteroarylmethyl or heteroarylmethoxy group, a methyl or methoxy group substituted by 1 to 3 fluorine atoms or a cyano, nitro or amino group, and**

**$R^3$ denotes a hydrogen, fluorine, chlorine or bromine atom or a methyl or trifluoromethyl group,**

Claim 1 of BI patent (cont'd)

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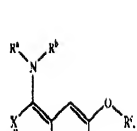

wherein

...Rc denotes

- a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R4-N-R5, while

R4 denotes a hydrogen atom or a C1-3-alkyl group and

R5 denotes a hydrogen atom or a C1-3-alkyl group,

an aminocarbonyl-C1-3-alkyl, C1-3-alkylaminocarbonyl-C1-3-alkyl, di-(C1-3-alkyl)aminocarbonyl-C1-3-alkyl, pyrrolidin-1-ylcarbonyl-C1-3-alkyl, piperidin-1-ylcarbonyl-C1-3-alkyl, homopiperidin-1-ylcarbonyl-C1-3-alkyl, morpholin-4-ylcarbonyl-C1-3-alkyl, homomorpholin-4-ylcarbonyl-C1-3-alkyl, piperazin-1-ylcarbonyl-C1-3-alkyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl-C1-3-alkyl, homopiperazin-1-ylcarbonyl-C1-3-alkyl or a 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl-C1-3-alkyl group,

a hydroxy-C2-4-alkyl, C1-3-alkyloxy-C2-4-alkyl, C1-4-alkyloxy-carbonylamino-C2-4-alkyl, amino-C2-4-alkyl, C1-3-alkylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-C2-4-alkyl, C1-3-alkylcarbonylamino-C2-4-alkyl, aminocarbonylamino-C2-4-alkyl, C1-3-alkylaminocarbonylamino-C2-4-alkyl, di-(C1-3-alkyl)amino-carbonylamino-C2-4-alkyl, pyrrolidin-1-ylcarbonylamino-C2-4-alkyl, piperidin-1-ylcarbonylamino-C2-4-alkyl, morpholin-4-ylcarbonylamino-C2-4-alkyl, C1-3-alkylsulphonyl-C2-4-alkyl or a C1-3-alkylsulphonylamino-C2-4-alkyl group,

a (2-oxo-pyrrolidin-1-yl)-C2-4-alkyl, (2-oxopiperidin-1-yl)-C2-4-alkyl, (3-oxo-morpholin-4-yl)-C2-4-alkyl, (2-oxo-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-3-C1-3-alkyl-imidazolidin-1-yl)-C2-4-alkyl, (2-oxo-hexahydropyrimidin-1-yl)-C2-4-alkyl or a (2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl)-C2-4-alkyl group,

a C1-4-alkylsulphonyl, chloro-C1-4-alkylsulphonyl, bromo-C1-4-alkylsulphonyl, amino-C1-4-alkylsulphonyl, C1-3-alkylamino-C1-4-alkylsulphonyl, di-(C1-3-alkyl)amino-C1-4-alkylsulphonyl, (pyrrolidin-1-yl)-C1-4-alkylsulphonyl, (piperidin-1-yl)-C1-4-alkylsulphonyl, (homopiperidin-1-yl)-C1-4-alkylsulphonyl, (morpholin-4-yl)-C1-4-alkylsulphonyl, (homomorpholin-4-yl)-C1-4-alkylsulphonyl, (piperazin-1-yl)-C1-4-alkylsulphonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkylsulphonyl, (homopiperazin-1-yl)-C1-4-alkylsulphonyl or a (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkylsulphonyl group, a C1-4-alkyloxycarbonyl group,

a formyl, C1-4-alkyl-carbonyl, C1-3-alkyloxy-C1-4-alkyl-carbonyl, tetrahydrofuranylcarbonyl, tetrahydropyranylcarbonyl, amino-C1-4-alkyl-carbonyl, C1-3-alkylamino-C1-4-alkyl-carbonyl, di-(C1-3-alkyl)amino-C1-4-alkyl-carbonyl, pyrrolidin-1-yl-C1-4-alkyl-carbonyl, piperidin-1-yl-C1-4-alkyl-carbonyl, (homopiperidin-1-yl)-C1-4-alkyl-carbonyl, morpholin-4-yl-C1-4-alkyl-carbonyl, (homomorpholin-4-yl)-C1-4-alkyl-carbonyl, (piperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-piperazin-1-yl)-C1-4-alkyl-carbonyl, (homopiperazin-1-yl)-C1-4-alkyl-carbonyl, (4-C1-3-alkyl-homopiperazin-1-yl)-C1-4-alkyl-carbonyl or a C1-3-alkylsulphonyl-C1-4-alkyl-carbonyl group,

a cyano, aminocarbonyl, C1-3-alkyl-aminocarbonyl, di-(C1-3-alkyl)aminocarbonyl, (C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, N-(C1-3-alkyl)-N-(C1-3-alkyloxy-C2-4-alkyl)aminocarbonyl, arylaminocarbonyl, pyrrolidin-1-ylcarbonyl, piperidin-1-ylcarbonyl, homopiperidin-1-ylcarbonyl, morpholin-4-ylcarbonyl, homomorpholin-4-ylcarbonyl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-ylcarbonyl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-ylcarbonyl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-ylcarbonyl, piperazin-1-ylcarbonyl, 4-C1-3-alkyl-piperazin-1-ylcarbonyl, homopiperazin-1-ylcarbonyl, 4-C1-3-alkyl-homopiperazin-1-ylcarbonyl, aminosulphonyl, C1-3-alkyl-aminosulphonyl, di-(C1-3-alkyl)amino-sulphonyl, pyrrolidin-1-yl-sulphonyl, piperidin-1-ylsulphonyl, homopiperidin-1-ylsulphonyl, morpholin-4-ylsulphonyl, homomorpholin-4-ylsulphonyl, piperazin-1-ylsulphonyl, 4-C1-3-alkyl-piperazin-1-ylsulphonyl, homopiperazin-1-ylsulphonyl or a 4-C1-3-alkyl-homopiperazin-1-ylsulphonyl group,

a cyclobutyl, cyclopentyl or cyclohexyl group which is substituted in each case by a group R6, where R6 denotes a 2-oxo-pyrrolidin-1-yl, 2-oxopiperidin-1-yl, 3-oxo-morpholin-4-yl, 2-oxo-imidazolidin-1-yl, 2-oxo-3-C1-3-alkyl-imidazolidin-1-yl, 2-oxo-hexahydropyrimidin-1-yl or a 2-oxo-3-C1-3-alkyl-hexahydropyrimidin-1-yl group,

- an azetidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a pyrrolidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-3-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined,
- a piperidin-4-yl group which is substituted in the 1 position by the group R5, while R5 is as hereinbefore defined, or
- a tetrahydrofuran-3-yl, tetrahydropyran-3-yl or tetrahydropyran-4-yl group,

Claim 1 of BI patent (cont'd)

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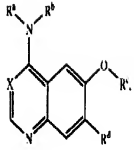


wherein

...$R^d$ denotes

a hydrogen atom or a fluorine, chlorine or bromine atom,

a hydroxy group,

a C1-4-alkyloxy group,

a methoxy group substituted by 1 to 3 fluorine atoms,

an ethyloxy group substituted by 1 to 5 fluorine atoms,

a C2-4-alkyloxy group which is substituted by a group R6 or R7, while

R6 is as hereinbefore defined and R7 denotes a hydroxy, C1-3-alkyloxy, C1-3-cycloalkyloxy, amino, C1-3-alkylamino, di-(C1-3-alkyl)amino, bis-(2-methoxyethyl)-amino, pyrrolidin-1-yl, piperidin-1-yl, homopiperidin-1-yl, morpholin-4-yl, homomorpholin-4-yl, 2-oxa-5-aza-bicyclo[2.2.1]hept-5-yl, 3-oxa-8-aza-bicyclo[3.2.1]oct-8-yl, 8-oxa-3-aza-bicyclo[3.2.1]oct-3-yl, piperazin-1-yl, 4-C1-3-alkyl-piperazin-1-yl, homopiperazin-1-yl or C1-3-alkyl-homopiperazin-1-yl group, or a formylamino, C1-3-alkylcarbonylamino, C1-3-alkyloxy-C1-3-alkyl-carbonylamino, C1-4-alkyloxycarbonylamino, aminocarbonylamino, C1-3-alkylaminocarbonylamino, di-(C1-3-alkyl)aminocarbonylamino pyrrolidin-1-ylcarbonylamino, piperidin-1-ylcarbonylamino, piperazin-1-ylcarbonylamino, 4-C1-3-alkyl-piperazin-1-ylcarbonylamino, morpholin-4-ylcarbonylamino or a C1-4-alkylsulphonylamino group,

a C3-7-cycloalkyloxy or C3-7-cycloalkyl-C1-4-alkyloxy group,

a tetrahydrofuran-3-yloxy, tetrahydropyran-3-yloxy or tetrahydropyran-4-yloxy group,

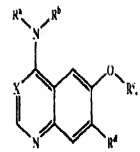
a tetrahydrofuranyl-C1-4-alkyloxy or tetrahydropyranyl-C1-4-alkyloxy group,

a C1-4-alkoxy group which is substituted by a pyrrolidinyl, piperidinyl or homopiperidinyl group substituted in the 1 position by the group R8, while

R8 denotes a hydrogen atom or a C1-3-alkyl group,

or a C1-4-alkoxy group which is substituted by a morpholinyl group substituted in the 4 position by the group R8, while R8 is as hereinbefore defined, and

Claim 1 of BI patent (cont'd)



(I)

wherein
...X denotes a nitrogen atom, and

by the aryl groups mentioned in the definition of the above groups is meant in each case a phenyl group which is mono- or disubstituted by R9, while the substituents may be identical or different and R9 denotes a hydrogen atom, a fluorine, chlorine, bromine or iodine atom or a C1-3-alkyl, hydroxy, C1-3-alkyloxy, difluoromethyl, trifluoromethyl, difluoromethoxy, trifluoromethoxy or cyano group,

by the heteroaryl groups mentioned in the definition of the above groups is meant a pyridyl, pyridazinyl, pyrimidinyl or pyrazinyl group, while said heteroaryl groups are each mono- or disubstituted by the group R9, while the substituents may be identical or different and R9 is as hereinbefore defined, and

said pyrrolidinyl, piperidinyl, piperazinyl and morpholinyl groups may be substituted in each case by one or two C1-3-alkyl groups, and

unless otherwise stated, said alkyl groups may be straight-chained or branched,

with the proviso that the compound 4-[(3-chloro-4-fluoro-phenyl)amino]-6((S)-tetrahydrofuran-3-yloxy)-7-hydroxy-quinazoline is excluded,

their tautomers, their stereoisomers, their mixtures and their salts.

## '991 Claims 39-43 are Patentably Distinct over Lost BI Claims 3-6

**Lost BI Claim 3-5 are drawn to 3- or 3,4- substitution on the phenyl ring**

**Lost BI claim 6 is drawn to 3,4- substitution on the phenyl ring**

**In contrast, '991 Claims 39-43 all recite 2,3-substitution on the phenyl ring**

# U.S. Application No. 10/571,991

**Response:**

Bradbury is not applicable prior art under 103(c) since Bradbury and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to AstraZeneca.

# U.S. Application No. 10/571,991

**Bradbury: Effective U.S. filing date is March 26, 2003 (PCT filing date)**

**Present application: Priority claimed to EP03292309.6, filed September 19, 2003 (i.e., less than a year after Bradbury's date)**

# U.S. Application No. 10/571,991

## Present Application:

### Claims drawn to:

- A compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(carbamoylmethyl) piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts

A pharmaceutical composition comprising at least one of compound chosen from 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-{[1-(carbamoylmethyl) piperidin-4-yl]-oxy}quinazoline and its pharmaceutically acceptable salts
in association with a pharmaceutically-acceptable diluent or carrier

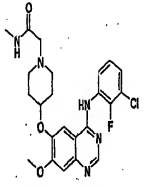
# U.S. Application No. 10/571,991

**Present application:** Priority EP03292309.6 contains § 112 support for the present claims



Example 1

Preparation of 4-(3-Chloro-2-fluoroanilino)-7-methoxy-6-[[1-(N-methylcarbamoylmethyl)piperidin-4-yl]methoxy]quinazoline



2-Chloro-N-methylacetamide (32 mg, 0.3 mmol) was added dropwise to a mixture of 4-(3-chloro-2-fluoroanilino)-7-methoxy-6-[(piperidin-4-yl)oxy]quinazoline (120 mg, 0.3 mmol), potassium iodide (16 mg, 0.1 mmol), and potassium carbonate (50 mg, 0.36 mmol) in acetonitrile (5 ml). The mixture was heated at reflux for one hour. After evaporation of the solvents under vacuum, the residue was taken up in dichloromethane. The organic solution was washed with water and brine, dried over magnesium sulfate. After evaporation of the solvents under vacuum, the residue was purified by chromatography on silica gel (eluant: 1% to 2% 7N methanolic ammonia in dichloromethane) to give the title compound as a white solid (85 mg, 60%).

# U.S. Application No. 10/571,991

**Present application:** Priority EP03292309.6 contains § 112 support for the present claims

19. A pharmaceutical composition which comprises a quinazoline derivative of the Formula I, or a pharmaceutically-acceptable salt thereof, as defined in any one of claims 1 to 17 in association with a pharmaceutically-acceptable diluent or carrier.

LEXSEE 359 F2D 859

# IN RE HANS HILMER, GERHARD KORGER, RUDI WEYER AND WALTER AUMULLER

**No. 7482***

* Petition for rehearing denied July 28, 1966.

**United States Court of Customs and Patent Appeals**

***53 C.C.P.A. 1288*; *359 F.2d 859*; *1966 CCPA LEXIS 420*; *149 U.S.P.Q. (BNA) 480***

**Oral argument November 2, 1965**
**April 28, 1966**

**PRIOR HISTORY:** [***1] APPEAL from Patent Office, Serial No. 750,887

**DISPOSITION:** Reversed and remanded.

**COUNSEL:** *Eugene O. Retter, John Kekich, George E. Frost, Henry W. Koster* for appellants.

*Clarence W. Moore (Joseph Schimmel,* of counsel) for the Commissioner of Patents.

**OPINION BY:** RICH

**OPINION**

[**861] [*1289] Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Jr., Associate Judges.

RICH, Judge, delivered the opinion of the court:

[1] The sole issue is whether a majority of the Patent Office Board of Appeals erred in overturing a consistent administrative [*1290] practice and interpretation of the law of nearly forty years standing by giving a United States patent effect as prior art as of a foreign filing date to which the patentee of the reference was entitled under *35 USC 119*.

Because it held that a U.S. patent, cited as a prior art reference under *35 USC 102(e)* and *103*, is effective as of its foreign "convention" filing date, relying on *35 USC 119*, the board affirmed the rejection of claims 10, 16, and 17 of application serial No. 750,887, filed July 25, 1958, for certain sulfonyl ureas.

This opinion develops the issue, considers the precedents, and explains why, [***2] on the basis of legislative history, we hold that *section 119* does not modify the express provision of *section 102(e)* that a reference patent is effective as of the date the application for it was "filed in the United States."

The two "references" relied on are:

| | | |
|---|---|---|
| Habicht (filed in the United States | | |
| January 23, 1958,found to be entitled | | |
| to priority as of the date offiling | | |
| in Switzerland on January 24, 1957) | 2,962,530 | Nov. 29, 1960 |
| Wagner et al. (filed in the United | | |

The rejection here is the aftermath of an interference (No. 90,218) between appellants and Habicht, a priority dispute in which Habicht was the winning party on a single count. He won because appellants conceded priority of the invention of the count to him. The earliest date asserted by appellants for their invention is their German filing date, July 31, 1957, which, we note, is a few months later than Habicht's priority date of January 24, 1957.

After termination of the interference and the return of this application to the examiner for further ex parte prosecution, the examiner rejected the appealed claims on Habicht, as a primary reference, **[***3]** in view of Wagner et al., as a secondary reference, holding the claimed **[**862]** compounds to be "unpatentable over the primary reference in view of the secondary reference which renders them obvious to one of ordinary skill in the art."

Appellants appealed to the board contending, inter alia, that "The Habicht disclosure cannot be utilized as anticipatory art." They said, "The rejection has utilized * * * the disclosure of the winning party as a basis for the rejection. The appellants insist that this is contrary to the patent statutes." Explaining this they said:

* * * the appellants' German application was filed subsequent to the Swiss filing date [of Habicht] but prior to the U.S. filing date of the Habicht application. The appellants now maintain that the Habicht disclosure cannot be utilized as anticipatory in view of *35 U.S.C. 119* which is entitled "Benefit of Earlier Filing Date in Foreign Countries: Right of Priority." This section defines **[*1291]** the rights of foreign applicants and more specifically defines those rights with respect to dates to which they are entitled if this same privilege is awarded to citizens of the United States. There is no question **[***4]** [but] that *Section 119* only deals with "right of priority." The section does not provide for the use of a U.S. patent as an anticipatory reference as of its foreign filing date. This interpretation of *Section 119* is also set forth in the Manual of Patent Examining Procedure (Section 715.01). The Manual refers to Viviani vs. *Taylor vs. Herzog, 72 USPQ 448*, wherein Commissioner Coe clarified the question of priority rights with respect to foreign and domestic filing.

Appellants further pointed out that, "The interference only decided the priority of the interference issue [i.e. the count]; there was no decision made nor was there any attempt to decide who was the inventor of the disclosure. The appellants readily admit the priority of Habicht as to the interference issue, but there is no admission as far as the remaining subject matter is concerned."

The board, one member dissenting with an opinion, affirmed the rejection. In the majority opinion there are four statements of the issue. The first is:

As stated by appellants in their reply brief, the main issue presented by this appeal is the availability of the Habicht patent as a reference. This question was argued at **[***5]** length at the hearing and appellants were requested to file, and filed, a further legal memorandum concerning it. [Emphasis ours.]

The third statement (second to follow later) involves an expression of the board's view on the relevance of the interference to the issue and reads:

It is noted that the instant application was involved in an interference with Habicht (before the patent issued), with claim 1 of the patent as the count, and appellants conceded priority to Habicht. However, no questions of estoppel or res judicata can be raised concerning the [presently claimed] cyclohexyl substituted compound; Habicht did not disclose (or even suggest) any cyclohexyl or cycloalkyl compounds, no count to a cyclohexyl compound, or broad enough to include cycloalkyl compounds could have been added to the interference, nor could appellants have relied on such compounds to show priority. Appellants are free to attempt to secure claims to such compounds and to show that they preceded Habicht's date as to them, the question being which date of Habicht is the controlling one. [Emphasis ours.]

We deemed this to be a clear statement that Habicht did not claim and could not have claimed [***6] the subject matter now claimed by appellants, that therefore there could have been no interference, or priority contest, with Habicht with respect thereto, that for this reason no estoppel or res judicata may be asserted against

appellants as a result of the [**863] interference, wherefore the question is the effective date of the Hibicht patent. [1]

> 1 The board's opinion contains no clear recognition of another rejection by the examiner, different from the rejection above stated, based on the issue of the interference in view of Wagner et al. This opinion deals only with the issue the board chose to deal with. As to the other rejection, see the end of this opinion under "Reason for Remand."

[*1292] The Board's fourth statement of the issue reads:

With respect to claims 10 and 16, the issue in this case is:

When the claimed subject matter of a U.S. patent is used as a basis for rejecting a claim in an application and the reference patent is found to be entitled to the date of a prior foreign [***7] application under *35 USC 119*, is the date of the reference which must be overcome, in order to remove it [as a reference], its actual filing date in the United States or the priority date to which the patent is entitled for that subject matter? [Emphasis ours.]

We note that there are two restrictions in this statement not present in any of the others. First, it refers only to claimed subject matter of the "reference" patent. That this was deliberate is shown by a footnote to the very end of the majority board opinion in which the majority said:

13. Whether the foreign filing date can be used for such matters as mere descriptions of prior art, disclosures of species not within the scope of any of the claims of the U.S. patent, etc., which may appear in the specification of the latter, is not decided since such matters are not involved herein.

As we see the facts here, however, the board relied on subject matter not claimed. We regard the restriction as without legal significance because: (1) *Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (1926)*, discussed infra, creating the rule of *35 USC 102(e)*, here relied on as basic support for the rejection, abolished [***8] the distinction between claimed and unclaimed disclosure; (2) within a few months of the decision herein the board decided *Ex parte Zemla, 142 USPQ 499 (1964)*, and Ex parte Rapala (unreported, Appeal No. 225-56, decided Sept. 18, 1964), discussed infra, in which this distinction is not mentioned, so that the board now seems to think, as do we, that, as a question of law, whether the disclosure is claimed is irrelevant. [2] Another reason why we shall disregard the limitation to claimed subject matter is that authority higher than the Patent Office, namely the *District Court for the District of Columbia in Eli Lilly & Co. v. Brenner, 248 F.Supp. 402, 147 USPQ 442 (1965)*, discussed infra, has effectively removed this restriction in a parallel case as shown in the quotation we later make from its opinion. Lilly was Rapala, supra, in the Patent Office.

> 2 See, however, footnote 1 and the section at the end of this opinion headed "Reason for Remand."

The second restriction in the Board's fourth statement of the [***9] issue is that "the reference patent is found to be entitled to the date of a prior foreign application under *35 USC 119* * * *." To some degree this loads the question. There is in it an implicit assumption that if the patent is "entitled to the date of a prior foreign application," it is entitled to it, and that is that. But one must examine closely into what is meant by the word "entitled." In essence, that [*1293] is the problem in this appeal and we wish to point to it at the outset to dispel any mistaken assumptions. A patent may be "entitled" to a foreign filing date for some purposes and not for others, just as a patent may be "used" in two ways. A patent owner uses his patent as a legal right to exclude others, granted to him under *35 USC 154*. Others, wholly unrelated to the patentee, use a patent, not as a legal right, but simply as evidence of prior invention or prior art, i.e., as a "reference." This is not an exercise of the patent right. This is how the Patent Office is "using" the Habicht patent. These are totally different [**864] things, governed by different law, founded on different theories, and developed through different histories.

We have seen [***10] that *35 USC 119* is involved with respect to the so-called "priority date" of the Habicht reference patent. The other statutory provision involved in this case, applicable to both of the references, is *35 USC 102(e)*. *Section 102* has been aptly described (Meyer article, infra) as containing "patent defeating provisions." They fall into two classes, events prior to an applicant's date of invention and events prior to filing his U.S. application, related respectively to the requirement of novelty and to provisions for loss of right through

delay in filing after certain events have made the invention public. Subsection (e) is one of the novelty provisions, one of the "conditions for patentability," and if the facts of an applicant's case bring him within it, his right to a patent is defeated. This subsection together with the heading and introductory line of the section reads:

*§ 102*. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless -

* * *

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, [***11] * * *. [Emphasis ours.]

[2] Thus, though both references here were patents copending with appellants' application, issuing after it was filed, 102(e) makes them available as of their U.S. filing dates which are earlier than appellants' U.S. filing date. However, since 102(e) refers to the applicant's date of invention, not to his filing date, he is entitled to an opportunity to establish his date of invention to show that his invention possessed statutory novelty when he made it. In this case appellants did this by showing that they filed a German application earlier than the U.S. filing dates of the references, specified in 102(e), and that they were entitled to its date for "priority" under *section 119*. This right is not in question. The board ruled:

Appellants have overcome the U.S. filing date of Habicht by claiming the benefit under *35 USC 119* of an application filed in Germany on July 31, 1957. The specification of this German application has been examined and is found [*1294] to contain a full disclosure of the subject matter of the claims, and the U.S. filing date of Habicht is considered overcome.

We can now summarize the issue and simultaneously state [***12] the board's decision. Continuing the above quotation, the board said:

The Examiner insists, however, that the effective date of the Habicht patent is January 24, 1957, the date of an application filed in Switzerland which is claimed by Habicht under *35 USC 119*. Appellants have not overcome this earlier date of Habicht. The issue is hence presented of whether the foreign priority date of a United States patent can be used as the effective filing date of the patent when it is used as a reference. [Emphasis ours, and this is the second statement of the issue by the board.]

* * *

Our conclusion is that the priority date governs * * *.

This is the decision alleged to be in error. We think it was error.

Background of the Issue as to the Availability of Habicht as a Reference

The issue in this case involves a question of statutory interpretation basic to the operation of the patent system.This issue has arisen because after decades of a uniform practice, and interpretation of law which has existed in part since 1903 and in whole since 1926, the Patent Office has made an abrupt about-face; having refused for at least 30 years, after expressly ruling on the question, to apply [***13] U.S. patents as references as of foreign "priority" dates, it has changed its [**865] practice as made manifest in an unknown number of board decisions. One of them is here on appeal. Another, as will presently appear, has been reviewed under *35 USC 145* in the District Court for the District of Columbia where the Patent Office was affirmed, *Lilly v. Brenner, supra.* A third has been published, *Ex parte Zemla, 142 USPQ 499*.

There has been a spate of writing on the question of law here involved, all of which we have read. The same ground has been plowed and replowed by authors as well as different panels of the Patent Office Board of Appeals. In chronological order, the following articles and opinions have appeared:

August 1963, "Effective Filing Dates of U.S. Patents Based on *35 U.S.C. Sec. 119*," by Leon Chasan and Frederick H. Rabin, 45 JPOS 601-612, attacking the problem "as to which date - the actual U.S. filing date or the earlier convention date - shall be considered as that of filing under *35 U.S.C. § 102(e)*." They conclude that "the answer to the question * * * is not free from doubt * * *." The closing sentence is: "It appears likely that the courts will have to [***14] rule expressly on this point, possibly in the near future, and it is also quite possible that the position taken by the Patent Office will be reversed." (Herein "Chasan-Rabin article.")

[*1295] February 25, 1964, the Hilmer opinion below, then unpublished, majority opinion by Examiner-in-Chief Federico joined by Acting Examiner-in-Chief Rosdol, dissenting opinion by then Acting Examiner-in-Chief Behrens, holding that the convention date is the effective date of a U.S. patent as a reference with respect to "claimed subject matter" therein and "the disclosure in the specification relevant to the claimed invention."

March 1964, "An Analysis of the Combined Effect of *35 USC § 119* and *35 USC § 102(e)*," by David S. Fishman of the Connecticut Bar, 46 JPOS 181-213, saying "this paper will attempt to demonstrate that such patents [claiming priority to a foreign filing date] should be accorded the foreign filing date for reference purposes * * *." In the context of the article this means as references to defeat claims to patents by all others and with respect to all matter disclosed whether or not claimed, and whether used to show complete anticipation or in support of a claim of [***15] obviousness *35 USC 102*, *103*. (Herein "Fishman article.")

May 27, 1964, a Commissioner's Notice issued (published June 9, 1964, 803 O.G. 305) revoking a very long-standing section of the Manual of Patent Examining Procedure (MPEP), 715.01 "Reference Claims Foreign Filing Date," based on a Commissioner's decision of May 9, 1935, Viviani v. *Taylor v. Herzog, 72 USPQ 448*, and providing that an applicant need not antedate the foreign filing date of a reference. The Notice stated that "foreign filing date is considered the effective date in those situations where claimed subject matter of the domestic patent (or disclosed matter related thereto) is being used as the basis for rejection, and where no question of interference exists."

June 8, 1964, this Hilmer appeal filed in this court with transcript of record making the board's opinion a public record.

July 31, 1964, decision rendered by the *Board of Appeals in Ex parte Zemla, supra*, opinion by Examiner-in-Chief Kreek, joined by Examiner-in-Chief Friedman and Acting Examiner-in-Chief Andrews, holding that a U.S. patent "may be used for all that it discloses as of the date that the same disclosure was made in a foreign country under [***16] the Convention." No mention is made of restriction to claimed subject matter or of any interference situation. The basis of the decision is a verbatim copy of the key segment of the Hilmer board opinion, but the limitations of the Hilmer decision are omitted and Hilmer is, of course, not mentioned.

August 1964, "Re: 'Ex parte Blumlein'," by Robert J. Patterson, 46 JPOS 597, calls attention to the omission in the Fishman article of a decision of this court, *In re Walker, 41 CCPA 913, 213 F.2d 332, 102* USPQ (1954), affirming *Ex parte* [**866] *Blumlein, 103 USPQ 223 (1952)*, reconsideration denied, *103 USPQ 224 (1953)*, which Fishman characterized as "completely untenable" and "logically [*1296] unsound" (pp. 205, 206), and saying: "One cannot but wonder if the author of the article would have said anything differently had he realized that the CCPA affirmed the Decision of the Board of Appeals."

August 1964, "Re: 'An USC *Section 119* and *35* USC USC *Section 119* and *35 USC Section 102(e)*'," by William E. Currie, 46 JPOS 598-599, expresses disagreement with the Fishman article and points to flaws in its reasoning. Currie points out that Fishman omits mention of the caption and [***17] the second paragraph of *section 119*, both of which refer to priority. Currie's view is that *section 119*, contrary to Fishman's view, thus does contain language restricting the meaning of the words "the same effect" so that they do not include effect as an "anticipation" but are limited to priority issues. Currie concludes:

Therefore, in view of this *Section 102(e)* should be read to mean just what it says, "filed in the United States." There is nothing in *Section 119* to carry over to *Section 102(e)*. Scope of the priority right is discussed in detail in "Foreign Priority Rights under *Section 119* of the Patent Act of 1952," Briskin, 39 JPOS 94-121.

Statutory enactment was required to prevent an applicant from establishing anticipation by using his foreign reduction to practice, but in that case there was no basis for interpretation, as there is here. It would seem to be illogical, and adverse to the interests of United States inventors, to give a foreign patent application the status of a reduction to practice for purposes of anticipation.

The last quoted paragraph refers, of course, to *35 USC 104*, which originated, as a statutory enactment, in section 9 of the Boykin Act, Aug. [***18] 8, 1946, 60 Stat. 943, both discussed infra.

September 18, 1964, decision rendered by the Board of Appeals in Ex parte Rapala (unpublished, Appeal No.

225-56, heard June 25, 1964), opinion by Examiner-in-Chief Federico joined by Examiner-in-Chief Rosa and Acting Examiner-in-Chief Stone. The opinion substantially duplicates the contents of Hilmer, contains the legal discussion used in Zemla, but like the latter does not limit the use of the disclosure of the U.S. patent held effective as of its British priority date to claimed subject matter or disclosure "relevant to" it. The following statement appears at the outset:

Appellant is aware of the fact that several recent decisions of the Board of Appeals have dealt with the question presented, but inasmuch as these decisions are not public they cannot be used as precedents and the question must be considered anew.

Therefore we find a repetition of most of the Hilmer opinion.As of now, of course, three board opinions are public. See Lilly v. Brenner, discussed infra.

November 1964, a Commentary, by Gary A. Samuels, 46 JPOS 827-828, critical of the Chasan and Fishman articles, the May 27 **[*1297]** Notice, and the Board **[***19]** of Appeals decision, expressing the view that the extension of the effective date of U.S. patents used as references backward in time to their foreign filing dates is contrary to the intent of Congress, referring to items of legislative history.

June 1965, "Are Patents Effective References as of Foreign Filing Dates?," by Harold S. Meyer of the Ohio Bar (Mr. Meyer was a member of the Coordinating Committee which helped to write the 1952 Patent Act - see Rich, "Congressional Intent - Or, Who Wrote the Patent Act of 1952?," pp. 61-78, Patent Procurement and Exploitation, BNA, Washington, 1963), 47 JPOS 391-410. Referring to all of the foregoing items, Meyer says: "Those publications and decisions which favor the foreign application date as the effective date of a reference have left out of consideration some significant factors which lead to exactly the contrary conclusion." His article develops this thesis in detail and concludes as to "what the law was intended **[**867]** to be when it was enacted as the present statute, and what it therefore is" in these words: "The provisions of the International Convention and *35 USC 119* * * * establish only priority rights for the claimed subject **[***20]** matter, and do not change the effective dates of references under *35 USC 102(a), (b),* and *(e).*" (Herein the "Meyer article.")

October 6, 1965, Manual of Patent Examining Procedure amended by inserting new section 715.01 corresponding in substance to the May 27, 1964 Notice and Hilmer.

November 1965, a Commentary, by L. Chasan (see August 1963, supra), 47 JPOS 922-924, on the Meyer article in which this co-author says his former position was that while the answer to the problem of statutory construction "was not free from doubt, on balance the case law and the authorities that have considered this have arrived at the conclusion that it is the Convention date which should control." He then tries to discredit some of Meyer's authorities, ignoring the mainstream of his argument and ends by saying:

The matter is of sufficient interest that even the forthcoming CCPA hearings on, e.g., In re Hilmer, Korger, Weyer and Aumuller, may not be conclusive. The issue will undoubtedly be raised in interparte [sic] matters of sufficient importance for possible ultimate resolution by the Supreme Court.

December 20, 1965, opinion of the District Court, District of Columbia, in Lilly v. Brenner, **[***21]** 147 USPQ 442-470. This was a suit under *35 USC 145* to review the decision of the board in Ex parte Rapala, supra, and so far as we know is the last item to date in the general picture. The opinion adopted by the District Court supports the granting of a summary judgment requested by the Patent Office dismissing Lilly's complaint. On the question of law presented, namely, the effective date of a single U.S. patent cited as a reference to support a rejection under *35 USC 103* for obviousness, **[*1298]** the court agreed with the Patent Office that the effective date was the convention filing date in Great Britain, a date the applicant could not overcome. Had the reference been held effective only as of its actual date of filing in the United States, as plaintiff urged, the Patent Office motion for summary judgment would have been denied. We have most carefully studied this opinion as it is the most recent decision dealing with all of the arguments which have been brought to bear on this problem, contributing not a few new ones. We cannot agree with it.

To make clear what we disagree with, we quote the District Court's own summary statement of its position (USPQ at 448):

[5] **[***22]** The important question to be settled in this case is one of first impression in this court. The issue

may be stated to be whether, in a situation where a foreign inventor has been granted a United States patent on a United States patent application which is entitled under *35 U.S.C. § 119* to the benefit of an earlier application filing date in a foreign country, this United States patent is available as a reference under *35 U.S.C. 102(e)* for all disclosed subject matter, whether claimed or unclaimed, as of the filing date of the earlier foreign application. This court agrees with defendant [Patent Office] and holds that the foreign filing date is the effective reference date as to all subject matter which is disclosed, whether claimed or not, in the foreign application, to the extent that such disclosures are brought forward and included in both the United States application and the United States patent granted on this application, the latter, of course, being the basis for a *35 U.S.C. § 102(e)* rejection. [Emphasis ours.]

We regret that we find ourselves in conflict with the District Court, especially with an erstwhile colleague, on a question of patent law, and correspondingly **[***23]** in disagreement with several members of the board, but we find ourselves in agreement with the Meyers article, with the Patterson, Currie, and Samuels **[**868]** commentaria, and with the dissenting views of Examiner-in-Chief Behrens who found the history of *sections 102* and *119* to give "scant comfort to the majority's interpretation." We find it indeed strange that it has suddenly become imperative to reinterpret a statute which was enacted in 1903, later construed in the light of a Supreme Court decision of 1926, and to invert a practice under which a generation of lawyers since the latter date has obtained for clients close to two million United States patents, counting for their validity on a construction of the statutory law not only followed but promulgated by the Patent Office. Furthermore, in 1952 this law, already a quarter of a century old in toto, was carried forward by Congressional action without change, insofar as it was already statutory, and insofar as it was case law it was codified without change, the particulars of which will be dealt with later. This change in long an continuous administrative practice has also been made without any advance notice, hearing, or **[***24]** stated basis in policy, economics, **[*1299]** or international relations. While it may be that the world is shrinking and the very concept of "foreign" should be abolished for the good of mankind, this is not a constitution we are expounding but specific statutes enacted to accomplish specific purposes, the meaning of which should stay put, absent intervening Congressional modifications, for well-understood reasons.

Turning from the general to the specific, we will now consider our specific reasons for construing the applicable statutes as they have for so long been construed, contrary to the recent innovation of the Patent Office.

OPINION

The District Court in Lilly opens its opinion by observing that the question before it was one of first impression in that court. Here it is otherwise. In 1954 this court decided *In re Walker, 41 CCPA 913, 213 F.2d 332, 102 USPQ 79*. The casual reader of the opinion alone might get the impression, as apparently the District Court did in Lilly (USPQ at 466), that Walker did not involve the issue here. On careful examination, especially with the aid of the record and briefs, it will be seen to be otherwise. Since it is the one case in **[***25]** point in this court we shall examine Walker first, after which we shall approach the problem of statutory construction primarily in a chronological fashion.

Walker was an appeal from the board decision in *Ex parte Blumlein, 103 USPQ 223 (1952)*, decided below prior to the effective date of the 1952 Patent Act but afterward in this court. The discrepancy in names is due to the death of Alan D. Blumlein, said to be a well known British TV inventor, and his U.S. application was filed by his executrix, Doreen Walker (formerly Doreen Blumlein). As here, Blumlein was given an invention date by reason of the priority statute (then R.S. 4887) as of the filing of his British application on June 5, 1942. Involved as a reference was a U.S. patent to Whiteley, the U.S. filing date of which, February 5, 1943, was after Blumlein's date but the British filing date of which was earlier, February 17, 1942. Blumlein was making the same contention in that case that appellants are making here, that as a reference the effective date of the Whiteley U.S. patent was its U.S. filing date. The board of appeals agreed with that contention. The board also expressly held that Whiteley's British priority **[***26]** date was of "no consequence," apart from the effect of the outcome of an interference between Blumlein and Whiteley.

In the interference with Blumlein, Whiteley was able to assert his priority date which enabled him to antedate Blumlein and win the interference on his claims 1 and 2. In subsequent ex parte **[*1300]** prosecution the examiner's rejection which went to the board was restated

in his Statement (now called an Answer) in these terms:

Whiteley is considered to be a valid reference for what it shows, since the decision in the above interference was adverse to applicant, and Whiteley [**869] proved a foreign filing date prior to applicant's foreign filing date.

* * *

* * * Applicant has failed to show any special circumstances whereby the Whiteley patent is not a reference against his claims.

In essence applicant argues that Whiteley is not an effective reference for what it shows, but only for what it claims. The effect of such a holding would be to grant applicant the benefit of his British filing date, but to deny it to Whiteley who successfully contested common subject matter with applicant.

The board, while agreeing with appellant's view that Whiteley [***27] was a reference only as of its U.S. filing date, gave a somewhat equivocal opinion about the effect of the interference, saying:

* * * we are of the opinion that in view of the adverse decision on priority, appealed claims 11 to 17 and 20 were properly rejected as unpatentable over the issue of the interference. Accordingly, we sustain the rejection of these claims.

Two subsequent opinions on reconsideration did not satisfy appellant, or clarify for him the exact ground relied on and in appealing to this court three questions were presented: (1) Whether the appealed claims were patentably distinct from claims 1 and 2 of Whiteley; (2) whether under *35 USC 119* Blumlein had to overcome Whiteley's British priority date; and (3) whether Blumlein was estopped by the interference from claiming the subject matter of his appealed claims. The court had to and did consider all three questions. This court's opinion expressly considers point "(2)" supra, as the argument "that 'By carrying his [Blumlein's] invention back of the domestic filing date of the application which matured into the Whiteley patent, the appellant overcame that patent as a reference for the integrating circuit which [***28] is disclosed but not claimed therein,' citing in support thereof the relevant provision of the code, *35 U.S.C. 119* * * *." (Emphasis ours.) The court answered the argument by quoting a paragraph from the Patent Office Solicitor's brief in which he conceded appellant to be correct, that as to structure not claimed by Whiteley it would be "quite permissible" to allow a claim to a later applicant who showed he invented the claimed structure before the filing date of the domestic application of Whiteley. The court then placed its own interpretation on the quoted paragraph saying, "In other words, the solicitor frankly concedes that appellant's quoted argument on the point in issue is 'absolutely correct, on the facts stated', but the solicitor contends, and we think properly, that appellant's argument is too broad and inapposite with respect to the case at bar." (Emphasis ours.)

[*1301] Having passed on that point, the court then proceeded, in effect, to pass on points "(1)" and "(3)", supra, and to hold that the claims were not patentably distinct from the claims lost by Blumlein in the interference and to say that was the true ground of the decision below, which it affirmed on [***29] that ground. We therefore have in this Walker-Blumlein case decisions by both the board and this court that as to non-interfering subject matter the foreign priority date of a U.S. reference patent is of "no consequence" and that only the United States filing date has to be overcome. The final decision adopted the first of three possible courses of action for the court as submitted in Walker's brief in the following words:

1. It may affirm the decision below on the ground that the appealed claims and the interference counts are for the same invention and that, therefore, they are res judicata as to the appellant.

But in the process of arriving at that course of action the court did pass on the law applicable where there is no res [**870] judicata, as in the present case. [3] The court's views at that time were in complete accord with the legal expertise in the Patent Office.

> 3 We trust this explanation of what this court did in Walker is a sufficient answer to the curiosity expressed by the District Court in Lilly (USPQ 467, col. 1) as to our "reaction" to the argument that we passed on a rejection not relied on by the Board of Appeals. This court did pass on the question as it was presented to it. The confusion as to what the ground of rejection actually was required the court to do so.

[***30] We note that in Lilly, in discussing Walker,

the court ignored all of the relevant matters discussed above and proceeded on the assumption it could not possibly have passed on a point on which it did pass. It also ignores the Blumlein decision in the Patent Office on the very issue here involved.

We further note that in the instant case the board's opinion finds "confusion" as to the ground on which this court in Walker sustained the rejection, which we think is clearly stated, and that the board errs in stating the contention of the solicitor and the court's supposed approval of it. The solicitor did not contend that all "subject matter recited in the [Whiteley] claims" was available as prior art as of the priority date. Far from it, he said in his brief, "The issue here in no way involves a foreign filing date of the patentee Whiteley. * * * The rejection here is not upon Whiteley's foreign filing date. The rejection is based upon the adverse award of priority * * *." That is what the court "indicated * * * was proper." We think the board erred further in reading the second opinion on reconsideration in Blumlein (which it refers to as "Walker") in saying that in that **[***31]** opinion "the foreign date was considered relevant with respect to the disclosed but unclaimed components of the combination claimed." We find nothing remotely resembling such a view. In a very short opinion in answer to several requests to **[*1302]** clarify its position, what the board did was to reiterate its position that Blumlein's claims were to subject matter "not patentably distinct" from the issue of the interference which he lost. It said nothing at all about "unclaimed components of the combination claimed," as stated by the board here.

On the other hand, appellants here rely on Walker and accurately state what happened in Blumlein and in Walker, contending it is precedent supporting their contention "that the domestic filing date of a patent obtained by a foreign applicant is the critical date to be considered when it is desired to use the patent for anticipation purposes," that is, as an ordinary prior art reference. We fully agree. For the same reasons, we disagree with the Lilly opinion (USPQ at 466) where it says: "the [Walker] case does not really support plaintiff's position."

The Patent Office Solicitor has nothing to say on Walker for the interesting **[***32]** reason that he did not really file a brief for the Patent Office position. In his brief he says:

Inasmuch as the decision [opinion] of the Board of Appeals sets forth in full and exact detail the reasons why the priority date is considered the effective date of the Habicht patent under *35 USC 102(e)*, it is believed to be unnecessary and undesirable to repeat or to paraphrase the decision in this brief.

In other words, the opinion of the board is the brief in this case. That was the position the solicitor took at oral argument.

We turn now to a chronological review and to the other statutes and precedents relied on by the parties.

The board's conclusion is that the foreign priority date of a U.S. patent is its effective date as a reference. In identical language in its opinion in this case and in the Zemla and Rapala (Lilly) opinions, the board's statement is:

Our conclusion is arrived at simply by considering *sections 102(e)* and the **[**871]** first paragraph of *section 119* of the statute together.

* * * [Here the statutes are quoted] * * *

*Section 119* refers to two applications for the same invention stemming from the same inventor, one a first application **[***33]** filed in a foreign country and the other a later application filed in the United States. * * * *Section 119* provides that under the specified circumstances, and subject to the requirements of the second paragraph which are not in question here, the second application, filed in the United States, "shall have the same effect" as it would have if filed in the United States on the date on which the application was filed in the foreign country. This language is plain; it gives the application the status of an application filed in the United States on a particular date. *Section 102(e)* provides that a patent may not be obtained if the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant. This paragraph makes the filing date of a U.S. patent [note the omission of "in the United States"] the effective date as a reference.It refers to an application filed in the United States and since *section 119* provides that the application shall have the same effect as if filed in this country **[*1303]** on a particular date, these two provisions must be read together and the filing date of the **[***34]** foreign application becomes the effective date of the United States reference patent. [Emphasis ours.]

This is so plausible that one's impulse is to say "Q.E.D." [4] We find the reasoning at fault, however, and the interpretation untenable. To discuss it we must have *section 119* before us, insofar as applicable:

> 4 This construction is reminiscent of the many misreadings of the former statutory definition of the patent rights as "the exclusive right to make, use, and vend the invention or discovery," R.S. 4884, which was so often asserted to give the patentee some positive right to make or use or sell things embodying his patented invention. The Supreme Court put this idea to rest in *Bloomer v. McQuewan, 55 U.S. 539, 549 (1852)*, but it did not die until the 1952 Act changed the statute to read "the right to exclude others from making, using, or selling the invention * * *." *35 USC 154*. Even now its ghost seems to hover over the opinion in the Lilly case (*147 USPQ at 451*, col. 2, 452.)

*§ 119*. Benefit **[***35]** of earlier filing date in foreign country; right of priority

An application for patent for an invention filed in this country by any per son who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

No application for patent shall be entitled to this right of priority unless [here follows the **[***36]** requirement for filing certain papers in the Patent Office and claiming priority not in question here, as the board held] * * *. [Emphasis ours.]

The board's construction is based on the idea that the language of the statute is plain, that it means what it says, and **[**872]** that what it says is that the application filed abroad is to have the same effect as though it were filed here - for all purposes. We can reverse the statement to say that the actual U.S. application is to have the same effect as though it were filed in the U.S. on the day when the foreign application was filed, the whole thing being a question of effective date. We take it either way because it makes no difference here.

Before getting into history, we note first that there is in the very words of the statute a refutation of this literalism. It says "shall have the same effect" and it then says "but" for several situations it shall not have the same effect, namely, it does not enjoy the foreign date with respect to any of the patent-defeating provisions based on publication or patenting anywhere in the world or public use or **[*1304]** being on sale in this country more than one year before the **[***37]** date of actual filing in this country. [5]

> 5 These patent-defeating one-year time-bars are also contained in *35 USC 102(b)* (formerly R.S. 4886) and have always been included in 119 (formerly R.S. 4887) to assure that it would not have the "same effect" if giving effect to a priority date would avoid these time-bars.

As to the other statute involved, we point out that the words of *section 102(e)*, which the board "simply" reads together with *section 119*, also seem plain. Perhaps they mean precisely what they say in specifying, as an express patent-defeating provision, an application by another describing the invention but only as of the date it is "filed in the United States."

[3] The great logical flaw we see in the board's reasoning is in its premise (or is it an a priori conclusion?) that "these two provisions must be read together." Doing so, it says 119 in effect destroys the plain meaning of 102(e) but the board will not indulge the reverse construction in which the plain words of 102(e) limit the **[***38]** apparent meaning of 119. We see no reason for reading these two provisions together and the board has stated none. We believe, with the dissenting board member, that 119 and 102(e) deal with unrelated concepts and further that the historical origins of the two sections show neither was intended to affect the other, wherefore they should not be read together in violation of the most basic rule of statutory construction, the "master rule," of carrying out the legislative intent. Additionally,

we have a long and consistent administrative practice in applying an interpretation contrary to the new view of the board, confirmed by legislation ratification in 1952. We will consider these matters separately.

*Section 119*

We shall now take up the history and purpose of *section 119*. The board opinion devotes the equivalent of four pages in the printed record to a scholarly and detailed review of the history of *section 119* with all of which we agree, except for the interwoven conclusions as to its meaning as it bears on the effective date of a U.S. patent used as a reference.

The board shows that the predecessor statute (R.S. 4887), containing the words "shall have the same force and [***39] effect," was enacted March 3, 1903 (32 Stat. 1225). Theodore Roosevelt signed it into law. The bill was drafted and proposed by a Commission created by Act of Congress in 1898 (30 Stat. 431) to study the effect of the Convention of Paris for the Protection of Industrial Property of 20th March 1883, which was under revision at Brussels even as the Commission deliberated, the revision being adopted at Brussels [*1305] on 14th December 1900. (It was last revised at Lisbon on 31st October 1958.) The Commission made a report November 27, 1900, printed in 1902, entitled "Report of the Commissioners Appointed to Revise the Laws Relating to Patents, Trademarks, and Trade Names, with Reference to Existing Conventions and Treaties," which is fairly descriptive of its purpose. The section entitled "The Revision of the Patent Law," which we have read, [**873] extends from page 6 to page 39.It begins by saying (p. 6):

We have found it desirable in considering the question of revision of the patent law to first consider what changes in the law are needed to give full force and effect to the treaty obligations which the United States has undertaken touching the protection of inventions [***40] made by the subjects or citizens of certain foreign countries. [Emphasis ours.]

Under the heading "Priority Under the Convention," it says (p. 12):

The second provision of the Convention to be noticed, and one which may be of very great advantage to those of our citizens who desire to secure patents in foreign countries for their inventions, is that contained in article 4, and relates to the so called "delay of priority," or "period of priority."

It then explained that in most countries no valid patent can be obtained if before the application is filed, the invention has been described in a printed publication, either in the country of application or even, as in the case of France and six other countries, in any country; that the same was true as to public use of the invention; and that the convention gives applicants in member countries a period (then 7 months, soon extended to 12) in which they can file applications in other countries after the filing in their own country and obtain valid patents notwithstanding publication or use in the interval and before the filing of the foreign application. This, it explained, is the "delay of priority." In plain English, it was the [***41] right of an applicant to have the foreign application treated at law as prior to the intervening publication or public use, though in fact it was not, by giving a right to that applicant to delay filing in the foreign country, instead of filing simultaneously with the home application. This is what today we call simply "Convention priority," or just "priority." The foreign filing date is the "convention date" or the "priority date."

This priority right was a protection to one who was trying to obtain patents in foreign countries, the protection being against patent-defeating provisions of national laws based on events intervening between the time of filing at home and filing abroad. Under the heading "Recapitulation of Advantages Secured by the Convention," the Commission said, so far as relevant here (p. 14-15):

The advantages to our citizens in the matter of patents directly afforded by the convention may be thus recapitulated.

[*1306] First. The enjoyment in foreign countries of equal rights with subjects or citizens of those countries.

Second. The "delay of priority" of seven months within which to file applications abroad after filing in this country.

Third. [***42] The privilege of introducing articles embodying the invention manufactured in this country into foreign countries to a certain extent without thereby causing the forfeiture of the patents taken out there.

Note the emphasis repeatedly placed in the Commission Report on advantages to United States citizens. It was felt we should do what was necessary to comply with the reciprocity provisions to enjoy the benefits of the convention for our own citizens. It was also believed that by reason of Opinions of Attorneys General, Vol. 19, 273, "the International Convention, in so far as the agreements therein contained are not in accordance with the present laws of the United States, is without force and effect; that it is not self-executing, but requires legislation to render it effective * * * and * * * it is our opinion that such legislation should be adopted * * *." (Report p. 19.)

Specific to the question here, the Commission Report says (p. 24):

We are, therefore, of the opinion that an amendment to the law should be made, providing that the foreign [**874] application shall have, in case an application is filed in this country by the applicant abroad within the specified [***43] period, the same effect as if filed here on the day it was filed abroad.

The board thinks this "shows the intention of the Commissioners" to create "a status of [an application] having been filed in the U.S. for all purposes * * *." (Emphasis ours.) In the context of this case, that means for the purpose of using a U.S. patent, obtained with a claim of priority, as a prior art patent to defeat the right of a third party to a patent on subject matter which does not patentably distinguish from anything that happens to be disclosed in such patent - or at least from anything disclosed "relevant to the [there] claimed invention," depending on which recent board opinion one looks at. We have read every word of the Commission Report looking for any suggestion of such a concept and have found none. All the board found was the above question. We deem it wholly inadequate as a basis for finding an intent to create a "status" for an application - to say nothing of the patent granted thereon - "for all purposes." There are other factors to consider which negative any such legislative intent.

There is another sentence in the Commission Report we should consider on page 26. It called [***44] attention to the fact that in most foreign countries the patent is granted to the first to apply and said:

The Convention has created an exception to the rule and made an application in any State of the Union for the Protection of Industrial Property of the same effect as an application in the country where an application is subsequently made within the time specified as a period of priority. [Emphasis ours.] [*1307] This couples very nicely with the wording of the first recommendation for a change in U.S. Laws on page 27 where it was said:

First. The application for a patent filed within seven 2 months of the filing of an application for a patent for the same invention in any foreign country which is a party to the International Convention should be given the same force as regards the question of priority that it would have if filed on the date on which the foreign application was filed. (Fn. 2: Extended to twelve months.) [Emphasis ours.]

[4] The Commission, page 36, recommended proposed legislation, which is, in substance, the amendment to R.S. 4887 which was passed and is, with no change in substance, what we have today in *section 119*. The proposed bill in the [***45] Commission Report was entitled "A BILL to give effect to treaty stipulations relating to letters patent for inventions." The Act passed was entitled "An Act to effectuate the provisions of the additional act of the International Convention for the Protection of Industrial Property." Throughout, the same phrase has always appeared, "shall have the same force and effect," until it was simplified in the 1952 condification to "shall have the same effect." This change was mere modernization in legislative drafting. The Revisers Note to the section says: "The first paragraph is the same as the present law with changes in language." The Federico Commentary on the 1952 Act, 35 U.S.C.A., says (p. 29):

This so-called right of priority was provided for in the second paragraph of R.S. 4887 which is the basis for the first paragraph of *section 119* of this title. * * * [he here states the 4 conditions for obtaining the right] * * * The new statute made no changes in these conditions of the corresponding part of the old statute except to revise the language slightly * * *. 6

> 6 In the two and a half page analysis of *section 119*, referred to always as giving a "right of priority," there is no hint that the foreign filing date has anything to do with the effective date of a U.S. patent as a prior art reference. The Commentary was published in 1954. Thus, the present interpretation by Mr. Federico, speaking as an Examiner-in-Chief, represents a later

development.

[***46] [**875] We need not guess what Congress has since believed to be the meaning of the disputed words in *section 119*, for it has spoken clearly. World wars interfere with normal commerce in industrial property. The one-year period of priority being too short for people in "enemy" countries, we had after World War I a Nolan Act (41 Stat. 1313, Mar. 3, 1921) and After World War II a Boykin Act. Foreign countries had reciprocal acts. One purpose was to extend the period of priority. House Report No. 1498, January 28, 1946, by Mr. Boykin, accompanied H.R. 5223 which became Public Law 690 of the 79th Cong., 2d Sess., Aug. 8, 1946, 60 Stat. 940. Section 1 of the bill, the report says, was to extend "the so-called period of priority," which then existed under R.S. 4887.On p. 3 the report says:

In this connection, it may be observed that the portion of the statute which provides that the filing of a foreign application - shall [*1308] have the same force and effect as the same application would have if filed in this country on the date on which the application for patent for the same invention, discovery, or design was first filed in such foreign country -

is intended to [***47] mean "shall have the same force and effect," etc., insofar as applicant's right to a patent is concerned. This statutory provision has no bearing upon the right of another party to a patent except in the case of an interference where the two parties are claiming the same patentable invention.

We emphasize none of those words because we wish to emphasize them all. We cannot readily imagine a clearer, more definitive statement as to the legislature's own view of the words "same effect," which now appear in *section 119*. This statement flatly contradicts the board's view. The board does not mention it.

In Lilly the District Court (USPQ at 461-463) attempts to depreciate the above quotation to the vanishing point by saying it is nothing but reiteration of an erroneous Commissioner's decision ( *Viviani, supra*), was not directly concerned with the Boykin Act, probably was not thoughtfully considered by the whole House or even the full committee, and is not a report on *section 119*, which was not enacted until six years later. If this need be answered, the answer is that the quotation happens to be a precise statement of the construction consistently placed on the statute by the Patent [***48] Office until 1963; [7] that the Boykin Act was concerned, as its first order of business in section 1, with extending the right of priority; and finally (omitting comment on the reading habits of Congressmen), *section 119* is the very same law as R.S. 4887, the statute about which the report was speaking and, in effect, amending. Presumably Mr. Boykin wished to make it clear to Congress and the public that if his bill passed, it would not be pushing the effective date [**876] of references back by several years into the fund of unknown applications reposing in foreign patent offices, waiting to have Boykin act counterparts filed in the U.S., which could have had a most serious effect on the validity of U.S. [*1309] patents issued in the war and post-war period, as well as on applications then pending. [8] R.S. 4887, the predecessor of *section 119*, is annexed to the report.

7 To show that this was still the established construction in 1959 we cite McCrady, Patent Office Practice, 4th Ed. (1959), Sec. 142, "Effective Date of Domestic Patent," at p. 198:

> Where the reference patent claims benefit of an earlier foreign filing date, it would seem that the validity of such claim cannot be precluded against an applicant except in an inter partes proceeding. Despite the language of *35 USC § 119*, that the U.S. application "shall have the same effect as the same application would have if filed in this country on the [foreign filing] date," the Office does not ordinarily use the foreign filing date in rejections n.56, although where the patentee has won an interference with applicant on the strength of his foreign filing date such date becomes the effective date of the patent as to claims similar to the interference counts. n.57
>
> n56 *Viviani v. Taylor (Comr: 1935) 72 PQ 448*, MPEP 715.01
>
> n57 *Ex parte Kinsella (BA: 1938) 39 PQ 199*. Ex parte Blumlein (BA: 1952 & 1953) *103*

*PQ 223*

> To the same effect was the Patent Office's own MPEP, section 715.01 as it was over a long period until changed on May 27, 1964, quoted infra.

8 [***49] We know section 1 of the Boykin Act has a saving clause about "conflicting" rights of applicants and patentees but under the law then existing believe it refers to interference situations, possibly, and note that it refers specifically to infringement situations. In 1946 U.S. patents were not used as "references" as of their foreign priority dates and "conflicting" would not have connoted such situations.

Another reason for giving great weight to the Committee Report's comments on what R.S. 4887 meant is that the same bill contained a section 9, the predecessor of present *35 USC 104*, discussed later, dealing expressly with acts of invention in foreign countries and overruling the effect of the Supreme Court decision in *Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5 (1939)*, all of which has a bearing on the problem before us. That section prohibits proof of acts abroad to establish a date of invention, except as *section 119* may have been complied with as to an application filed abroad.

[5] For the foregoing reasons, we are clearly of the opinion that *section 119* is not to be **[***50]** read as anything more than it was originally intended to be by its drafters, the Commission appointed under the 1898 Act of Congress, namely, a revision of our statutes to provide for a right of priority in conformity with the International Convention, for the benefit of United States citizens, by creating the necessary reciprocity with foreign members of the then Paris Union.

The board has mentioned that it was not limited in its terms to that treaty, which is true, so that it also functions relative to other treaties and reciprocal laws. We are unable to deduce from this any intent to affect the date as of which U.S. reference patents are effective. Nor can we do so by reason of another "deviation" from the Convention the board finds in section 4887 (now 119) as to the protection of third parties.

*Section 102(e)*

[6] We have quoted this section above and pointed out that it is a patent-defeating section, by contrast with *section 119* which gives affirmative "priority" rights to applicants notwithstanding it is drafted in terms of "An application." The priority right is to save the applicant (or his application if one prefers to say it that way) from patent-defeating provisions **[***51]** such as 102(e); and of course it has the same effect in guarding the validity of the patent when issued.

*Section 102(e)*, on the other hand, is one of the provisions which defeats applicants and invalidates patents and is closely related in fact and in history to the requirement of *section 102(a)* which prohibits a patent if

> **[*1310]** (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, * * *. [Emphasis ours.]

In fact, *section 102(e)* springs straight from 102(a)'s predecessor, R.S. 4886, by decision of the United States Supreme Court in 1926.It was pure case law until 1952 when, having become firmly established, that law was codified by incorporating it in the statute.

We will not undertake to trace the ancestry of 102(e) back of its immediate parentage but clearly it had ancestors or it would never have come to the Supreme Court. We will regard its actual birth as the case of *Alexander Milburn Co. v. Davis-Bournonville Co., 270 U.S. 390 (March 8, 1926)*, which we shall call Milburn. It is often called the Davis-Bournonville [***52] case. It was an infringement suit on a patent to Whitford and the defense, under R.S. 4920, was that he was not the first **[**877]** inventor. R.S. 4920, "Fourth" defense, was: "That he was not the original and first inventor or discoverer of any material and substantial part of the thing patented." This was based on that part of R.S. 4886 corresponding to present 102(a), which read, "not known or used by others in this country, before his invention or discovery thereof". (Emphasis ours.) Defendant produced a patent to Clifford which contained a full description of Whitford's invention, but did not claim it. The law at that time was in confusion as to whether claiming was relevant to the defense and that was the issue the Supreme Court resolved. The Circuit Courts were in conflict, especially the Second and Sixth. No foreign applications were involved. The U.S. filing date of the application for Clifford's patent was earlier than

any date relied on by Whitford. In a short three and a half page opinion Mr. Justice Holmes held that the description of Whitford's invention in Clifford's patent, Clifford's application having been filed in the United States Patent Office with the **[***53]** same description before Whitford's invention, showed that Whitford was not the first inventor, as the law required, and that his patent was therefore invalid.

We need not go into the reasoning of the Milburn case, which has its weaknesses, because all that matters is the rule of law it established: That a complete description of an invention in a U.S. patent application, filed before the date of invention of another, if it matures into a patent, may be used to show that that other was not the first inventor. This was a patent-defeating, judge-made rule and now is *section 102(e)*. The rule has been expanded somewhat subsequent to 1926 so that the reference patent may be used as of its U.S. filing date as a general prior art reference, as shown by *In re Harry, 51 CCPA 1541, 333 F.2d 920, 142* USPQ (1964), and the December 8, 1965 **[*1311]** Supreme Court decision in *Hazeltine Research, Inc. v. Brenner, 382 U.S. 252, 147 USPQ 429*.

What has always been pointed out in attacks on the Milburn rule, or in attempts to limit it, is that it uses, as prior knowledge, information which was secret at the time as of which it is used - the contents of U.S. patent applications which are preserved **[***54]** in secrecy, generally speaking, *35 USC 122*. This is true, and we think there is some validity to the argument that that which is secret should be in a different category from knowledge which is public. Nevertheless we have the rule. However, we are not disposed to extend that rule, which applies to the date of filing applications in the United States, the actual filing date when the disclosure is on deposit in the U.S. Patent Office and on its way, in due course, to publication in an issued patent.

The board's new view, as expressed in this case and in the Zemla and Rapala decisions, the latter sustained in Lilly, has the practical potential effect of pushing back the date of the unpublished, secret disclosures, which ultimately have effect as prior art references in the form of U.S. patents, by the full one-year priority period of *section 119*. We think the Milburn rule, as codified in *section 102(e)*, goes far enough in that direction. We see no valid reason to go further, certainly no compelling reason.

We have seen that *section 119* originated in 1903 and that its purpose was to grant protective priority rights so that the United States might be a participating member in **[***55]** the International Convention by giving reciprocal priority rights to foreign applicants with respect to the obtaining of patents. We have also seen that *section 102(e)* was the codification of a court-developed patent-defeating rule based on a statutory requirement that an applicant's invention must not have been previously known by others in this country. We see no such relation between these two rules of law as requires them to be read together and it is our view that *section 119* should not be so read with 102(e) as to modify the express limitation of the latter to applications "filed in the United States."

**[**878]** *Section 104*

[7] This brings us to another related section of the statute. We noted above that *section 102(a)* refers to knowledge of an invention in this country as a patent-defeating provision. This had been interpreted, long before the 1952 codification, to mean public knowledge. Federico's Commentary, 35 U.S.C.A. p. 18 says:

> In the language of paragraph (a), an invention is not new if it "was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant **[***56]** for patent." The Committee Report both in the general part and in **[*1312]** the Revision Notes recognizes that the interpretation of this condition is somewhat more restricted than the actual language, stating "the interpretation by the courts excludes various kinds of private knowledge not known to the public," and the narrowing interpretations are not changed. The first clause of paragraph (a) indicates that prior knowledge or use in foreign country will not defeat the right to a patent; a separate section, R.S. 4923 *[section 72* of former Title 35], in the old statute duplicated this provision and this old section has been omitted as its provisions are covered here and elsewhere. [Emphasis ours.]

The "elsewhere" is *section 104* which has also superseded section 9 of the 1946 Boykin act, above discussed. Before quoting it, we will mention another patent-defeating provision, 102(g) which says a patent may not be obtained on an invention if "before the applicant's invention thereof the invention was made in this country by another who had not abandoned,

suppressed, or concealed it." (Emphases ours.) The first sentence of *section 104* reads:

*§ 104.* Inventions made abroad.

[***57] In proceedings in the Patent Office and in the courts, an applicant for a patent, or a patentee, may not establish a date of invention by reference to knowledge or use thereof, or other activity with respect thereto, in a foreign country, except as provided in *section 119* of this title.

The second sentence is an exception not relevant here.

[8] It seems clear to us that the prohibitions of 104, the limitations in *sections 102(a)* and *102(g)* to "in this country," and the specifying in 102(e) of an application filed "in the United States" clearly demonstrate a policy in our patent statutes to the effect that knowledge and acts in a foreign country are not to defeat the rights of applicants for patents, except as applicants may become involved in priority disputes. We think it follows that *section 119* must be interpreted as giving only a positive right or benefit to an applicant who has first filed abroad [9] to protect him against possible intervening patent-defeating events in obtaining a patent. Heretofore it has always been so interpreted with the minor exceptions, of little value as precedents, hereinafter discussed. So construed, it has no effect on the effective date [***58] of a U.S. patent as a reference under *section 102(e)*.

9 [9] It is first filing in a foreign convention country that creates the priority right, not the nationality of the applicant. It often happens that American inventors domiciled in the United States file abroad before filing here and claim priority rights in their own country as a result.

As further indication that the Milburn rule never applied to foreign filing dates, and that its statutory version, *section 102(e)*, does not either, is the fact that the Supreme Court dealt with the matter.The lower court had attempted to draw an analogy involving R.S. 4887 on the issue whether the anticipatory subject matter had to be claimed. Mr. Justice Holmes said, "The policy of the statute as to foreign inventions obviously stands on its own footing and cannot [*1313] be applied to domestic affairs." (*270 U.S. at 402.*) This shows he was at least conscious of the fact that he was [**879] dealing only with "domestic affairs." In discussing this point, [***59] the Lilly opinion (*147 USPQ at 453*) emphasizes that it is dealing with a 102(e) rejection, involving disclosure which is in a U.S. patent, a rejection "not based on 102(a)." This rather overlooks the fact that Milburn rested on the proposition that Whitford was not the first inventor, that there was no 102(e) in those days, and that the court found the basis for its decision in the R.S. 4886 provision that the invention must not have been "known * * * by others in this country, before his invention * * *." Today this provision is 102(a).

[10] The simple observable fact, therefore, is that the effect of *section 102(e)* is to make a U.S. patent available as a reference, as of its U.S. filing date, and that thereafter the rejection of an application, or the holding of invalidity in the case of a patent, is predicated on some other section of the statute containing a patent-defeating provision to which the reference applies. [11] Much confused thinking could be avoided by realizing that rejections are based on statutory provisions, not on references, and that the references merely supply the evidence of lack of novelty, obviousness, loss of right or whatever may be the ground of [***60] rejection. In some cases we have examined on this issue, Walker-Blumlein for example, the statutory ground of rejection was that the applicant was not the first inventor, the evidence of that fact being that he lost a count to the same invention, or one patentably indistinguishable from it, in an interference. Yet the "reference relied on" in Walker-Blumlein was the patent granted to Whiteley after the interference, which patent had no relevance as such. There were similar aspects to the present case prior to the board's decision.

*Section 120*

At oral argument the Patent Office Solicitor argued by "analogy" from *35 USC 120* (a section which he said gives one U.S. application the benefit of an earlier U.S. application under specified circumstances for all purposes) that *section 119* should similarly give to a patent, used as a reference under *section 102(e)*, effect as of an earlier foreign filing date.

We could ignore the issue because it was not before the board here and was not briefed but will consider it because it is extensively discussed in Lilly (*147 USPQ at 449, 445, 462*) wherein the Patent Office pursued the same argument. One aspect of it is that *sections 119* and *120* [***61] contain the "same phrase," namely "shall

have the same effect."

[*1314] We find no substance in this argument because: (1) as above pointed out, our statute law makes a clear distinction between acts abroad and acts here except for patents and printed publications. *Section 120*, following policy in *sections 102(a)*, *(e)* and *(g)* and *104*, contains the limitation to applications "filed in the United States," excluding foreign applications from its scope. (2) Use of the same expression is mere happen-stance and no reason to transfer the meaning and effect of *section 120* as to U.S. filing dates to *section 119* with respect to foreign filing dates. *Section 120* was not drafted until 49 years after the predecessor of *section 119* was in the statute.

The Cases

With minor exceptions, we deem the few decided cases, which the writers on this issue all discuss, to be of slight significance. What determines the result in this case is statutory history, not judicial precedents. We will therefore treat them as briefly as possible in chronological order. Milburn (1926), of course, is part of the statutory history and does not deal with the issue here at all.

Next came *Federal Yeast* [***62] *Corp. v. Fleischmann Co., 13 F.2d 570 (4th Cir. 1926)*, affirming *8 F.2d 186 (D. Md. 1925)*. This was an infringement suit on two patents the validity of which was attacked. The court determined that they were for the same invention and they were both owned by Fleischmann. They could [**880] not both be valid. One of them had a 1915 German filing date, effective under the World War I Nolan Act, and a U.S. filing date in 1920. The other had a filing date in 1919. The patent on the former application was sustained and the patent on the latter application held invalid. There is much dispute as to what the case stands for. If the inventions were the same, as they appear to have been, a priority-type situation existed in which the date of priority and foreign filing would be involved. There was no interference, but in holding valid the patent with the German filing date the court gave the patent the benefit of the "priority" date. It also relied on Milburn, then just decided, subsequent to the District Court decision. The lower court found the patent with the German filing date to be the "prior application" by virtue of the Nolan Act, without discussion, said the respective [***63] filing dates fixed the dates of invention, found the second invention was the equivalent of the first, and under the authorities found there was "no patentable invention" in the second, wherefore it was invalid. The appellate court affirmed, saying validity was "to be governed by the ordinary rules" and finding, as to the second patent, "in view of the disclosures of Hayduck [the first], their claims in suit cover nothing [*1315] patentable." It also found the two inventions were the same and remarked that "the plaintiff can get all the relief against the defendant [from the claims of the one patent] it could obtain, if both patents were held valid and infringed." While we are not sure what the case stands for, other than the proposition that there cannot be two valid patents on the same invention, we are sure there was no discussion of the problem before us now. We are willing to say on its facts it is some support for the board but it seems to us more like a priority case or a double patenting issue than a decision on the effective date of a U.S. patent as a reference. In fact, the appellate court talked about "priority." On the issue here it is a very unclear precedent, [***64] as most commentators seem to agree.

Nine years pass without a decision and we then come to Viviani v. *Taylor v. Herzog, 72 USPQ 448 (1935)*, a Patent Office decision which deals squarely with the issue here, is admitted by the board in Rapala (Lilly) to be "of course contrary to the holding herein" whereas in this case the board attempts to distinguish it on the ground there is a difference between matter claimed in a reference and matter not claimed. We quote what the Commissioner said to show the basis of the Patent Office practice for some 30 years.

Section 4887 R.S. [119] does not concern itself with bars against the issuance of patents in this country, such bars being found in section 4886 R.S. [102] (*U.S.C., title 35, sec. 31* [old 35]).

Section 4887 R.S. relates solely to the rights of an applicant in the United States who has filed an antecedent and corresponding application in a foreign country.

* * *

In view of the origin of that [second] paragraph of the section [4887], it is believed to have the same meaning as if it had read, "shall have the same force and effect, in so far as applicant's right to a patent is concerned." This statutory provision [***65] has no bearing upon the right of another party to a patent except in the case of an interference where the two parties are

claiming the same invention.

* * *

Section 4887 R.S. cannot be construed as giving greater effect [to a foreign application, which at most is evidence of knowledge of the invention abroad] than is accorded by section 4923 R.S. to knowledge or use in foreign countries which is actually proven. [The last pair of brackets, inexplicably, appears in the original.]

The Commissioner considered the Fleischmann case, explaining at length why he found the basis of the decision unclear, noting that R.S. 4923 had not been mentioned. That old section, somewhat like *35 USC 104*, ruled out knowledge or **[**881]** use in a foreign country as a ground for invalidating a patent. See *Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5 (1939).*

**[*1316]** Under Viviani the Patent Office promulgated section 715.01 of its Manual of Patent Examining Procedure under which it and the bar operated until recently. It read:

In overcoming, under Rule 131, a domestic patent where the patentee has an earlier foreign filing date to which he would be entitled in establishing **[***66]** priority to the invention claimed in the patent, it is not necessary for the applicant to carry his date back to the patentee's foreign filing date. ( Viviani v. *Taylor v. Herzog, 72 U.S.P.Q. 448). [Emphasis ours.]*

In 1941 the Court of Appeals for the Second Circuit decided *Celanese Corp. of America v. Ribbon Narrow Fabrics Co., 117 F.2d 481, 48 USPQ 447*, affirming *33 F.Supp. 137, 45 USPQ 492 (S.D.N.Y. 1940)*. Suit was on a Dreyfus patent and a reference was a U.S. patent to Sponholz with a U.S. filing date after, and an alleged German filing date before, Dreyfus' date of invention. The wording of both opinions is inept and all writers are confused by it but whatever the statements made and reasons given, it is clear that defendant asserted the German filing date for the reference and the District Court refused it, the Court of Appeals saying "Sponholz had previously applied for a German patent on May 11, 1926 but that is immaterial * * *." It may be a precedent of little value but it is certainly on the side of disallowing the foreign filing date as the effective date of a reference patent.

In *1951 Young et al. v. General Electric Co., 96 F.Supp. 109, 88 USPQ 174*, was decided **[***67]** by an Illinois District Court. It involved validity of a patent in suit and the only pertinent remark is concerned with a Bethenod reference having a U.S. filing date after and a French filing date earlier than the date of invention of the patent in suit. Many other prior art patents were relied on. In footnote 6, USPQ at 195, in a 25 page opinion Judge Barnes said, speaking of Bethenod,

* * * whether it is prior art as to Young No. 2,179,569 depends on the date to which the Bethenod patent is entitled * * *. The court is of the opinion that it is entitled to the earlier date * * * but there is a difference of opinion on this question among the authorities. [Fleischmann and Celanese, supra, cited.] Whether Bethenod be regarded as prior art in this case makes little or no difference. There is a wealth of prior art without it.

This is some support for the board's view, but not much.

Most writers do not bother with the 1952 opinions of the Second Circuit Court of Appeals in Van der *Horst Corp. v. Chromium Corp., 197 F.2d 791, 93 USPQ 350*; *198 F.2d 748, 94 USPQ 288*. The court made the mistake of using, "Under the doctrine of Alexander Milburn," the British filing date of **[***68]** a British patent cited as prior art. On rehearing, the court, in effect, withdrew that ruling saying, **[*1317]** "It is not necessary to decide the point and we leave it open * * *." The stated reason for withdrawal was:

We failed to take into consideration *§ 72 of Title 35, U.S.C.A.* which provided that it should not "void" a patent that "the invention or discovery" had been previously "known or used in a foreign country, * * * if it had not been patented or described in a printed publication." It is reasonable to assume that Holmes, J., had *§ 72* in mind in *Alexander Milburn Co. v. Davis-Bournonville Co., supra, 270 U.S. at page 402*, * * * when he said that "The policy of the statute as to foreign inventions obviously stands on its own footing and cannot be applied to domestic affairs."

The statute referred to as *§ 72* is R.S. 4923. Cf. *35 USC 104*.

*Ellis-Foster Co. v. Reichhold Chemicals, Inc., 198 F.2d 42, 94 USPQ 16 (3rd Cir. 1952)*, is cited in the Fishman article as significant because, in his opinion, it criticizes Viviani, which we do not find to be the case.

The [**882] board herein in a footnote says that the patentee in Ellis-Foster failed to antedate the actual [***69] U.S. filing date of the reference patent, wherefore the issue here was not present. We agree.

The last case was in 1960 and at argument the solicitor indicated that it may have been what triggered the reconsideration of the law by the Patent Office and its subsequent change of position. *It is Sperry-Rand Corp. v. Knapp-Monarch Co., 193 F.Supp. 756, 127 USPQ 193 (E.D. Pa. 1961).*The examiner here relied on it. The board seems to give it great weight here and in Rapala (Lilly), finding in it the key phrase which is now its guiding principle - that *section 119* gives "status to an application." The District Judge [10] had a problem with a Wimberger patent cited as prior art, whether it was effective as of its Austrian filing date or only as of its U.S. filing date. He called for authority on the point and counsel for both sides supplied it in letters, with arguments, copies of which we have. Counsel for Sperry-Rand presented the "status" argument, which is its origin, so far as we have seen, based on the "same effect" words in *section 119*. The only cases he cited as authority for his view were Young, Ellis-Foster, and van der Horst, all discussed above. The court decided, in a footnote, [***70] that *section 119* gives "status to an application, as distinguished from mere benefit to an applicant, based on the foreign filing. This status is not limited in its effects to the particular applicant involved. Consequently, the Wimberger patent must be considered." His footnote mentions none of his reasons for so deciding, other than the words of *section 119*, cites no cases, and does not discuss the matter further.Viviani was called to his attention as well as MPEP 715.01.

> 10 Senior Judge William H. Kirkpatrick, United States District Court for the Eastern District of Pennsylvania, who often sits with this court and is so sitting now, but who did not sit in this case.

[*1318] With regret and for the reasons we have fully explained, we must simply express disagreement with the decision of the single judge in Sperry-Rand. Like the view of the board, we view his construction of the words of the statute as too literal and in disregard of the history of the law which was not called to his attention. As [***71] to its lack of compelling force as a precedent, we quote from the board herein:

> There was a rehearing in which the Court held that it was incumbent on the patentee to produce strong and convincing evidence of any prior date asserted, regardless of the Patent Office acceptance of an affidavit antedating references, *129 USPQ 305, 193 F.Supp. 756 (1961)*. There was no evidence in court, and hence the patentee had not overcome the filing dates of the other references involved, not even the U.S. filing date of the Wimberger patent. The issue involved here hence became moot and the statements of the Court regarding it are dicta, although this does not mean that they are incorrect. [Emphasis ours.]

Summary as to the Law and Its Legislative Ratification

We have now set forth extracts and digests of the materials produced by legal research to indicate what we believe the "law" to be. This, of course, is no substitute for the much more voluminous original materials. From it the following clear picture emerges.

[12] *Section 102(e)* was a codification of the Milburn doctrine. The Milburn case accorded a U.S. patent effect as a reference as of its U.S. filing date and stated that [***72] the policy of the statute on domestic inventions "cannot be applied to foreign affairs." No foreign date was involved in the case. The codifying statute specifies that the date as of which the patent has effect is the date of filing "in the United States."

R.S. 4887, predecessor of *section 119*, was in effect from 1903 to 1952 when it was incorporated unchanged in the present statutes. An examination of the legislative history of that statute fails to reveal a scintilla of evidence that it [**883] was ever intended to give "status" to an application or to serve as a patent-defeating provision except insofar as the application, or patent issuing thereon, becomes involved in a priority contest. The Milburn rule, under which U.S. patents are used as prior art references for all matter disclosed in them as of their U.S. filing dates has been consistently and continuously applied since its inception in 1926, if not earlier under lower court decisions, by the United States Patent Office, the agency charged with the administration of the patent system in accordance with the view expressed by the Commissioner of Patents in 1935 in the Viviani case. That view was that R.S. 4887, and [***73] later *section 119*, does not make a U.S. patent effective as a reference as of a foreign priority date to [*1319] which it may be entitled. This view was further actively promulgated by the Patent Office in the first edition of its Manual of Patent Examining Procedure, Section 715.01, November,

1949, and so continued until May 27, 1964, after the expression by the board of its new view as exemplified in this case.

There is no case "law" on the issue here worth considering. Some seven cases have been cited pro and con, the most that can be found in a period of thirty-four years from 1926 to 1960. We believe they can be accurately summarized as follows: Van der Horst is concededly not in point. There are three cases cited as favoring the board's position here: Fleischmann is a doubtful precedent of uncertain meaning where one of two patents on a single invention was invalidated on the basis of a priority date to which the other was held entitled; a single judge in Young thought the priority date of a patent was its effective date as a reference, recognizing conflict as between two precedents; a single judge in Sperry-Rand, briefed on prior cases in letters from counsel but **[***74]** not on the statutory history, took the same view as the board here. On the other side there are also three cases: Viviani refusing to follow Fleischmann and expressly holding that the priority statute does not apply to the effective date of a reference; Celanese where a Court of Appeals refused to apply the priority date to a reference and said it is "immaterial"; and Walker-Blumlein where this 5-judge appellate court held that only the domestic filing date of a reference is effective, in which case the Patent Office Solicitor conceded that to be the law.

If any "weight of authority" is to be found in this we would say the scales tip more than perceptibly in favor of the restriction of U.S. patents as references to their filing dates in the United States, as stated in *section 102(e)* and in accordance with "in this country" limitations of 102(a), (g), and the prohibitions of *section 104*.

[13] But over and above this as a basis of decision we feel there is a paramount principle which controls. The administrative agency known as the Patent Office pursued a uniform policy and interpretation contrary to the new view of the board for the 26 years from 1926 to 1952, at least. The **[***75]** interpretation was well publicized and well known and must be assumed to have been known to Congress in 1952 when it revised and codified the patent statutes into present Title 35, United States Code. In that codification *section 119* reenacted R.S. 4887 with no change in substance, as above shown.

This legislative ratification of the interpretation of the statutes by the Patent Office determines the meaning and effect of *section 119* for the future. *Helvering v. Winmill, 305 U.S. 79 (1938)*, *United States v. Dakota-Montana Oil Co., 288 U.S. 459 (1933)*. Under that interpretation, **[*1320]** *section 119* does not affect the express provision of 102(e) as to filing "in the United States" and the decision of the board that the Swiss filing date of Habicht is the effective date of his U.S. patent as a reference must be reversed.

Reason for Remand

As our analysis of the board's statements of the issue shows, the board concerned itself with a single question of **[**884]** law, the effective date of the Habicht patent as a reference under *35 USC 102(e)* and *103*. The only other question it dealt with was the merits of the rejection, having found Habicht to have an early enough date **[***76]** to be available as a reference. On the merits, it found the invention of all three appealed claims to be obvious within the meaning of *35 USC 103*. We have not considered that finding because of our decision that Habicht is not available as a prior art reference, which makes it unnecessary to pass on the merits of the rejection based on Habicht in view of Wagner et al.

Claim 17 was rejected only on the disclosure of Habicht in view of Wagner et al. and since we have held Habicht to be unavailable, the rejection of that claim stands reversed.

As to claims 10 and 16, however, the examiner made an additional rejection (in his Answer it was the only rejection of these two claims) as "unpatentable over the count of Interference No. 90,218 now claim 1 of the Habicht patent in view of the Wagner et al reference." (The language is quoted from the examiner's Answer.) So far as we can see, the board failed to deal with this rejection. The only possibility that the board dealt with the rejection on the interference issue is in the paragraph we quoted early in this opinion and described as the board's "third statement" of the issue. We are unable to say whether the board agreed or disagreed **[***77]** with the examiner's rejection on the interference issue in saying "no questions of estoppel or res judicata can be raised concerning" the claimed compounds of appellants.

Since the board predicated its affirmance of the examiner's rejection entirely on its finding that Habicht was available as a reference to show what the statutory prior art was, since we are reversing on that issue, and since we are unable to ascertain the board's decision, if

any, on the other outstanding rejection, we remand this case for clarification of the board's position on the rejection of claims 10 and 16 as "unpatentable over" the interference count in view of Wagner et al.

The decision of the board is reversed and the case is remanded for further proceedings consistent herewith.

**[*1321]** MARTIN, J., took no part in the decision of this case.

**DISSENT BY:** WORLEY

**DISSENT**

WORLEY, Chief Judge, dissenting.

It seems to me the majority below has the better of the argument with the majority here. Typical of my misgivings regarding the reasoning and conclusion of the present majority is the effort to fashion In re Walker into a controlling precedent for its position. It would be highly presumptuous of me **[***78]** to assume that merely because of my participation in that decision I became an authority on what the court held. It would be equally presumptuous to assume that I at once became an expert on Congressional intent merely as one of 435 members of the House of Representatives which passed by Boykin Act, or perchance as one of many who suggested or opposed language in that or other measures. The real test of judicial or legislative intent lies in the language employed. What the court held in Walker is found in its decision, and what Congress intended is found in the statute. In Walker this court expressly said:

The rejection by the tribunals of the Patent Office in the case at bar is based not upon the filing date of Whiteley's foreign application but upon the adverse award of priority of invention against appellant and in favor of Whiteley, the patentee. (Emphasis supplied).

Thus all else is obviously dicta.

There is no real judicial precedent in the cases cited below or here, save the **[**885]** recent District Court opinion [1] in Eli Lilly v. Brenner where the issue was squarely raised and properly disposed of. [2] In view of the unsettled and conflicting case law when the **[***79]** 1952 Patent Act was passed, it is not possible to ascertain which line of decisions Congress was "legislatively ratifying." Nor am I convinced that under such circumstances Congress was ratifying the then Patent Office practice. [3]

1 The author of that opinion is Judge Joseph R. Jackson who rendered distinguished service on this court for many years. He participated in Walker, and rejected it as precedent on the issue in Lilly.

2 See also Sperry-Rand Corp. v. Knapp-Monarch Co. to the same effect, although that discussion is, as in Walker, dicta.

3 The oft-repeated statement that administrative construction of a statutory provision receives legislative approval by reenactment of the provision without material change covers the situation where ambiguities in a statute are resolved by reference to administrative practice prior to reenactment.It does not mean that an interpretation of a provision of one act becomes frozen into another act merely by reenactment of that provision, so that administrative interpretation cannot be changed prospectively through exercise of appropriate administrative discretion. See *Helvering v. Wilshire Oil Co., 308 U.S. 90*. Nor does it mean that prior construction has become so embedded in the law that only Congress can effect a change. *Helvering v. Reynolds, 313 U.S. 428*. Moreover, any assumed acquiescence of Congress to the Patent Office interpretation of RS 4887 prior to its 1952 enactment of *Section 119* would appear of little import, absent evidence that that interpretation was expressly called to the attention of Congress at the time and expressly adopted. See Sutherland Statutory Construction, § 5109 (3 ed. 1943).

**[***80]** Granted the desirability of following the status quo, this court has never been reluctant to depart, in some instances sua sponte, from **[*1322]** that principle. [4] Thus there is no valid reason in law or logic why this court should prevent the Patent Office from correcting, on its own, what it obviously recognizes to be prior misinterpretation of Congressional intent.

4 See, e.g., *Shoe Corp. of America v. Juvenile Shoe Corp. of America, 46 CCPA 868, 266 F.2d 793, 121 USPQ 510*, reversing Patent Office practice and judicial precedent which had stood for over 30 years. See also *In re Bremner, 37 CCPA 1032, 182 F.2d 216, 86 USPQ 74*; *In re*

*Nelson, 47 CCPA 1031, 280 F.2d 172, 126 USPQ 242*; *In re Wilke, 50 CCPA 964, 314 F.2d 558, 136 USPQ 435*; *In re Palmquist, 51 CCPA 839, 319 F.2d 547, 138 USPQ 234*; *In re Manson, 52 CCPA 739, 333 F.2d 234, 142 USPQ 35*, many of which are discussed in *Brenner v. Manson, 383 US 519 (1966)*.

While it has been said (see *Bate Refrigerating Co. v. Sulzberger, 157 U.S. 1*; *Webster* [***81] *v. Luther, 163 U.S. 331*) that the practical construction given to an act of Congress, fairly susceptible of different constructions, by an executive department of the Government is entitled to respect, and in doubtful cases should be followed by the courts especially where interests have grown up under the practice adopted, it seems to me the meaning of the statute is clear and no prior practice inconsistent with that meaning can be given effect. See *Andrews v. Hovey, 124 U.S. 694, 716-718*. Antecedent administrative interpretation long in force does not render it impossible for the Patent Office to promulgate a new interpretation changing for the future the earlier practice, particularly when the new interpretation appears to comport with the plain meaning of the statute. See *American Chicle v. U.S., 316 U.S. 450*. *Section 119* states that a United States application based on a foreign application "shall have the same effect as the same application would have if filed in this country on the date on which the application * * * was first filed in such foreign country." There is no language in *Section 119* to restrict that effect in any way, whether for purposes of obtaining a patent or [***82] subsequently utilizing that patent as a prior art reference, i.e. evidence of priority as to the disclosed subject matter, to defeat another's right to a patent. It seems to me the majority here legislates into the [**886] statute words of limitation which Congress has not placed there. That it cannot do. Bate Refrigerating Co. v. Sulzberger; *Electric Storage Battery Co. v. Shimadzu, 307 U.S. 5, 14*.

I would affirm.

LEXSEE 977 F2D 1449

**IN RE HARRY C. DECKLER**

**92-1110**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

*977 F.2d 1449; 1992 U.S. App. LEXIS 26006; 24 U.S.P.Q.2D (BNA) 1448; 93 Daily Journal DAR 684*

**October 14, 1992, Decided**

**SUBSEQUENT HISTORY:** As Corrected October 23, 1992. Petition for Rehearing Denied and In Banc Suggestion Declined November 25, 1992, Reported at *1992 U.S. App. LEXIS 31713*.

**PRIOR HISTORY:** [**1] Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals & Interferences

**DISPOSITION:** AFFIRMED

**COUNSEL:** Fred S. Lockwood, Lockwood, Alex, Fitzgibbon & Cummings, of Chicago, Illinois, argued for appellant. With him on the brief was Raymond M. Mehler.

Fred E. McKelvey, Office of the Solicitor, of Arlington, Virginia, argued for the appellee. With him on the brief were Richard E. Schafer and Jameson Lee.

**JUDGES:** Before NIES, Chief Judge, FRIEDMAN, Senior Circuit Judge, and MAYER, Circuit Judge.

**OPINION BY:** FRIEDMAN

**OPINION**

[*1450] FRIEDMAN, *Senior Circuit Judge.*

The sole issue in this appeal from the Board of Patent Appeals and Interferences (Board), is whether the Board correctly ruled that the losing party in an interference proceeding was not entitled to a patent covering claims that that party admits are patentably indistinguishable from the claim involved in the interference. We affirm.

I

The appellant Deckler seeks a patent for an improved seed planter. In an interference proceeding under the "old" rules between Deckler and Grataloup, involving a claim the examiner had suggested to Deckler, the Board awarded priority of invention to Grataloup. The Board determined that although Deckler was first to reduce the invention [**2] to practice, he suppressed the invention until after Grataloup's priority date obtained by filing a foreign patent application. Grataloup subsequently was issued a patent on his invention, Claim 11 of which corresponds to the interference count.

Deckler's application was returned to ex parte prosecution. The examiner rejected all remaining claims, giving numerous grounds for rejection. In Deckler's appeal of claims 1-9, the Board reversed all but one of the rejections. The Board affirmed the examiner's rejection of claims 1 through 3 and 7 on the ground that the decision in the interference precluded Deckler from allowance of those claims, because they define the same invention as the interference count.

In his opening brief, Deckler challenged both the Board's conclusion that "the subject matter of claims 1 through 3 and claim 7 are not patentably distinct from the subject matter of the lost count," and the rejection based

on estoppel by judgment. In his reply brief and at oral argument, however, Deckler withdrew the first contention, [*1451] thereby in effect conceding that the claims on appeal are not patentably distinct from the interference count. The sole issue on appeal therefore is [**3] the propriety of the rejection of his claims based on the preclusive effect of the interference judgment.

II

A. 1. In rejecting Deckler's claims, the examiner relied on the Board's decision in *Ex parte Tytgat, 225 USPQ 907 (Bd. Pat. App. Int. 1985)*. In that case, Tytgat, like Deckler here, lost in an interference proceeding in which priority was awarded to the other party based on a foreign application filing date, and his application was returned to ex parte prosecution. The examiner rejected all remaining claims "on the ground of judicial doctrine and/or interference estoppel." *Id. at 908*.

An augmented Board panel upheld the rejection. *Id. at 909*. It first concluded that the subject matter of Tytgat's claims on appeal was "not patentably distinct" from the subject matter of the interference counts on which he lost. *Id. at 910*. The Board stated that "if a patent containing [Tytgat's] claims on appeal is issued to Tytgat, those claims and at least [four] claims . . . of [the interfering patent] would define a single inventive concept (i.e., would not be patentably [**4] distinct)." *Id.* The Board then explained its rationale for relying on the judgment in the interference and "general principles of res judicata and collateral estoppel" to reject Tytgat's claims:

> We think it most unlikely that Congress could have intended for two patents to be issued to different parties for a single inventive concept. Thus, we think it unlikely that Congress could have intended for a patent to be issued to Tytgat under the circumstances present here.

*Id. at 911*.

The rejection avoided the undesirable result that "if the judgment involving the 'lost' counts of the . . . interference cannot be used to reject the claims on appeal, a *second* interference will have to be declared between those claims and the claims of the [interfering] patent." *Id.* (emphasis in original). The second interference would involve a priority dispute over the same patentable subject matter to which the winning party was awarded priority in the first interference. The Board concluded that such a result would be unfair to the winning party in the original interference, and would be inconsistent with the general principle of res judicata that a judgment [**5] should settle finally all issues that were decided or should have been decided. *Id. at 912-13*.

2. In the present case, as in *Tytgat,* the Board relied on the judgment in the interference to reject claims patentably indistinct from the lost count. The Board concluded that

> if the judgment involving the "lost" count of the interference can not be used to reject claims 1 through 3 and 7 which are not patentably distinct from the lost count, a second interference will have to be declared between those claims and the claims of Grataloup. Furthermore, this interference would be declared with respect to subject matter identical to the subject matter of the count in the original Deckler/Grataloup interference.

Deckler acknowledged at oral argument that the count in a second interference between Deckler and Grataloup involving Deckler's claims 1-3 and 7 would be the same as the count in the first interference.

3. The judgment in the interference in this case awarded Grataloup priority of invention over Deckler--a result Deckler does not challenge--and resulted in the issuance of a patent to Grataloup that included the claim corresponding to the interference [**6] count. Since Deckler has in effect conceded that the subject claims in his application are patentably indistinguishable from his claim corresponding to the interference count, the Board properly concluded that the interference judgment barred Deckler from obtaining a patent containing those claims. As the Court of Customs and Patent Appeals pointed out in *Aelony v. Arni, 547 F.2d 566, 570, 192 USPQ 486, 490 (CCPA 1977)*, "*sections 102, 103*, and [*1452] *135* of 35 U.S.C. clearly contemplate--where different inventive entities are concerned--that only one patent should issue for inventions which are either identical to or not patentably distinct from each other." The court also noted that the patent statute intends that "only one patent should issue for one inventive concept." *Id.*

The Board's decision that the interference judgment bars Deckler from obtaining a patent for claims that are patentably indistinguishable from the claim on which Deckler lost the interference constituted a permissible application of settled principles of res judicata and collateral estoppel. Under those principles, a judgment in

an action precludes relitigation of claims [**7] or issues that were or could have been raised in that proceeding. *Federated Dep't Stores v. Moitie, 452 U.S. 394, 398,* (1981); *Montana v. United States, 440 U.S. 147, 153-54 (1979)*; *Foster v. Hallco Mfg. Co., 947 F.2d 469, 475-76, 20 USPQ2d 1241, 1246 (Fed. Cir. 1991)*. Similarly, this court has applied interference estoppel to bar the assertion of claims for inventions that are patentably indistinct from those in an interference that the applicant had lost. *In re Kroekel, 803 F.2d 705, 231 USPQ 640 (Fed. Cir. 1986)*; *Woods v. Tsuchiya, 754 F.2d 1571, 225 USPQ 11* (Fed. Cir.), *cert. denied, 474 U.S. 825 (1985)*.

The interference judgment conclusively determined that, as between Deckler and Grataloup, Grataloup was entitled to claim the patentable subject matter defined in the interference count. It is therefore proper, and consistent with the policies of finality and repose embodied in the doctrines of res judicata and collateral estoppel, to use that judgment as a basis for rejection of claims to the same patentable invention.

The Board correctly noted the unfortunate consequences [**8] that would follow if the interference judgment were not given that preclusive effect. There would be a second interference between Deckler's claims "and the claims of Grataloup. Furthermore, this interference would be declared with respect to subject matter identical to the subject matter of the count in the original Deckler/Grataloup interference." The Board should not be required to conduct such an unfair and cumbersome process unless the governing statutes, regulations or judicial decisions compel it. We discern nothing in them that so requires.

4. Deckler argues that because *35 U.S.C. § 135(a)* states that the Commissioner "may" declare an interference, it does not follow that a second interference would necessarily ensue. The Commissioner, however, has stated that such an interference would be declared, and we have no reason to reject that conclusion. Since both Deckler and Grataloup would have claims defining the same patentable subject matter, only an interference could determine priority of invention with respect to them.

B. Deckler contends that three decisions of our predecessor court, the Court of Customs and Patent Appeals, the decisions of which [**9] bind us, *South Corp. v. United States, 690 F.2d 1368, 1369-71, 1* Fed. Cir. (T) 1, 1-3, *215 USPQ 657, 657-58 (1982)* (in banc), require a contrary conclusion. Although the factual situations out of which those cases developed are similar to the situation in the present case, the grounds of decision in those cases were quite different from those of the Board in the present case. Those cases do not control this case, and we decline to extend their reasoning to require rejection of the Board's rationale in the present case.

The first case was *In re Hilmer, 359 F.2d 859, 149 USPQ 480 (CCPA 1966)*. Habicht was awarded priority over Hilmer in an interference, based on Habicht's foreign filing date, which was earlier than Hilmer's United States filing date. The Board then upheld the examiner's subsequent rejection of Hilmer's remaining claims as obvious under *35 U.S.C. § 103*. The Board relied primarily on the Habicht disclosures, which it held *35 U.S.C. § 119* made prior art because of Habicht's earlier foreign filing date.

The Court [**10] of Customs and Patent Appeals reversed. Noting that the Board had concluded that "the foreign priority date of a U.S. patent is its effective date as a reference," *id. at 870, 149 USPQ at 489*, the court held that "*section 119* does not modify the express provision of *section 102(e)* that a reference patent is effective as of the date the application for it was 'filed in the United States.'" *Id. at 861, 149 USPQ at 482*. The court remanded the case for the Board to clarify its position on two other claims in the application, the validity of which the Board did not decide. *Id. at 884, 149 USPQ at 501*.

The second case grew out of the remand, in which the Board rejected as obvious Hilmer's two other claims, on the ground that the subject matter of claim 1 of Habicht's patent was prior art under *35 U.S.C. §§ 102(g), 119*, and *104* as of Habicht's foreign filing date.

[*1453] The Court of Customs and Patent Appeals again reversed. *In re Hilmer, 424 F.2d 1108, 165 USPQ 255 (CCPA 1970)*. Noting [**11] that "the rejection here is under *§ 103* for obviousness," *id. at 1110, 165 USPQ at 257*, the court held that the subject matter of Habicht's claim was prior art under *section 102(g)*, if at all, as of Habicht's U.S. filing date, and could not in fact be prior art with respect to Hilmer because Hilmer's U.S. filing date preceded Habicht's. *Id. at 1110, 1112-13, 165 USPQ at 256, 258-59*.

In the third case, *In re McKellin, 529 F.2d 1324, 188*

*USPQ 428 (CCPA 1976)*, the "sole issue" before the court was "whether claims may be rejected under *35 U.S.C. § 103* on the ground that a losing party to an interference is not entitled to claims which are asserted to be obvious variations of the invention defined in the counts, when *section 102(g)* and interference estoppel are not applicable." *Id. at 1325, 188 USPQ at 430.*

McKellin had lost an interference in which the winning party prevailed solely on the basis of a foreign priority date. The Board rejected McKellin's remaining claims under *section 103* **[**12]** as unpatentable in view of the counts of the interference or in view of the disclosure of the interfering patent. The court reversed, holding that because the interference was decided solely on the basis of the winning party's right to the benefit of an earlier foreign filing date, there was no *"statutory* basis for finding that either the subject matter of the lost counts or the disclosure of the [interfering] patent is prior art, in the sense of *35 U.S.C. § 103*, to [McKellin]." *Id. at 1329, 188 USPQ at 434* (emphasis in original). In so holding, the court also rejected the Commissioner's theory that the count was statutory prior art under *35 U.S.C. § 135(a)* for purposes of *section 103. Id. at 1327, 188 USPQ at 432.*

In a concurring opinion, Judge Rich, the author of the two prior *Hilmer* opinions, "emphasize[d] that there clearly is no rejection before us other than a *§ 103* obviousness rejection." *Id. at 1334, 188 USPQ at 437.*

The issue in each of those cases was the validity of an obviousness **[**13]** rejection based upon the Board's holdings, on various grounds in the different cases, that under the governing statute the foreign filing date could not be used to make the patent prior art for obviousness purposes.

In the present case, in contrast, there was no obviousness rejection. The Board's sole ground of rejection was that under principles of res judicata and collateral estoppel, Deckler was not entitled to claims that were patentably indistinguishable from the claim on which he lost the interference. Indeed, in this case, the Board, citing *McKellin,* reversed the examiner's "rejections based on obviousness where Grataloup is used in a rejection under *§ 103*, inasmuch as the lost count is not a bar to appellant's claims and Grataloup is not prior art with respect to appellant."

Unlike the situation in those three cases, here the Board did not use the interference count as prior art in making an obviousness determination, but based its decision on a wholly different theory. We decline to extend those decisions to the different issue in this case.

**[*1454]** CONCLUSION

The decision of the Board is

AFFIRMED

LEXSEE 225 USPQ 907

Ex parte Daniel Tytgat, Lucien Clerbois and Stephane Noel

Appeal No. 577-74 from Art Unit 144.

Application for Patent filed June 12, 1978, Serial No. 914,724, a Continuation of Serial No. 713,810, filed August 12, 1976; now abandoned.

Process for Polimerization of Halogenated Vinyl Monomers in Aqueous Dispersion with Metal Halides.

Board of Patent Appeals and Interferences

*1985 Pat. App. LEXIS 28; 225 U.S.P.Q. (BNA) 907*

September 24, 1984, Heard
February 5, 1985, Decided

[*1]

Before Serota, Blech, Goldstein, Seidleck and McKelvey, Examiners-in-Chief.

**COUNSEL:**

Sheldon I. Landsman for appellants.

Primary Examiner - Joseph L. Schofer.

**OPINIONBY:** McKELVEY

**OPINION:**

McKelvey, Examiner-in-Chief

This appeal is from an examiner's final rejection of claims 1, 8-17, 19, and 20, all the claims remaining in the application on appeal.

The Invention

The invention relates to a method of polymerizing vinyl chloride in a reactor wherein build-up of undesirable material on the inner surfaces (e.g., the walls and stirrer) of the reactor is minimized. According to appellants (Tytgat) this build-up can be minimized by exposing an aqueous solution of a build-up inhibitor to the inner surfaces. The specific build-up inhibitors said to be useful for Tytgat's purpose are the alkali metal iodides, e.g., potassium iodide and sodium iodide.

The following discussion on page 7, lines 1-20 of the specification explains the invention:

When using a batch process it is preferable to expose the inner surfaces of the reactor to an aqueous solution containing the . . . iodide ions before the . . . [vinyl choride is] introduced into the reactor. Thus the reactor can be purged with the aqueous solution in such **[*2]** a way that a whole of the internal surface is treated, after which the solution is discharged and the normal polymerization ingredients introduced (water, dispersing or emulsifying agent, [vinyl chloride] monomers, initiator). When operating in this way it will be found that the preliminary purging is sufficient to coat the inner surfaces of the reactor with an adequate amount of . . . iodide ions by adsorption and it is not essential to add further ions to the aqueous dispersion during polymerization. However, for case of operation the Applicants prefer to introduce, first of all, the water used during polymerization which contains the . . . iodide ions in solution and may optionally contain other water-soluble ingredients such as the emulsifying or dispersing agents. The ions remain in the aqueous phase throughout polymerization. The . . . vinyl [choride] monomers together, optionally, with the initiator are not added until later.

Claim 1 is representative and reads:

1. Process for the polymerization in a batch reactor of vinyl chloride in aqueous dispersion with an initiator consisting essentially of a monomer-soluble free radical polymerization initiator and in the presence **[*3]** of a build-up inhibitor, wherein prior to charging the vinyl chloride in the reactor for the purposes of polymerization, its inner surfaces are exposed to an aqueous solution of a build-up inhibitor selected from iodide ions which are supplied in the form of alkali metal iodides.

Publications and Patents Cited

The examiner cited and relied upon two U.S. patents:

| | | |
|---|---|---|
| Aruga et al. (Aruga) | 3,997,707 | December 14, 1976 |
| Koyanagi et al. (Koyanagi) | 4,180,634 | December 23, 1979 |

Tytgat cited (Paper No. 31, filed January 21, 1983) what he refers to as "a copy of a summary of Japanese Patent Application 76/85716 of July 19th, 1976, published January 31st, 1978, under the name of Koyanagi . . ." See Paper No. 31, page 4, last paragraph.

The Examiner's Rejection

The examiner entered two rejections.

All the claims were rejected "on the ground of judicial doctrine and/or interference estoppel over Koyanagi patent."

All the claims were also rejected "on the ground of judicial doctrine and/or interference estoppel combined with Aruga."

These rejections are set out in more detail in the final rejection entered November 29, 1982 (Paper No. 30).

We will affirm the examiner's **[*4]** decision rejecting the claims. Since our rationale may be different than the rationale used by the examiner, we will designate our decision as having been made under 37 CFR § 1.196(b).

Background

The Koyanagi patent discloses a method of preventing build-up in a vinyl chloride polymerization reactor by adding to the polymerization reactor a build-up inhibitor. The inhibitor may be alkali metal iodide. See e.g., col. 1, line 64 through col. 2, line 2; col. 3, lines 23-30 and lines 40-44; and claims 1, 2, 3, and 9 (col. 6).

In 1981, Interference No. 100,649 was declared between the application on appeal and the Koyanagi patent. The four counts of the interference were as follows:

Count 1: A method of polymerizing vinyl chloride or a monomer mixture containing vinyl chloride as a main component, in an aqueous suspension in a polymerization reactor, which comprises adding at least one additive selected from the group consisting of iodine salts of alkali metals and alkaline earth metals to a polymerization mixture in said reactor.

Count 2: A method of count 1, wherein said alkali metals are selected from sodium and potassium and said alkaline earth metal is calcium. [*5]

Count 3: The method of count 1, wherein the amount of said additive is present in the range of between about 3 to 5,000 p.p.m. by weight based on the weight of said vinyl chloride or monomer mixture in said polymerization mixture.

Count 4: The method of count 1, wherein said iodine salts are selected from the group consisting of sodium iodide, potassium iodide, and calcium iodide.

At the time the interference was declared, Koyanagi claimed, but was not accorded, the benefit of a Japanese patent application filed July 18, 1975. Tytgat was accorded the benefit of an application filed in Luxembourg on August 18, 1975. The respective filing dates of Koyanagi and Tytgat are set out in Table 1.

Table 1

| | U.S. Filing Date | Foreign Filing Date |
|---|---|---|
| Koyanagi | 07-14-76 | 07-18-75 |
| Tytgat | 08-12-76 | 08-18-75 |

During the interference, Koyanagi moved (Paper No. 6 in the interference file) to be accorded the benefit of the filing date of the Japanese patent application in accordance with *35 U.S.C. 119.* The motion was opposed by Tytgat (Paper No. 9 in the interference file). A reply (Paper No. 10 in the interference file) was filed by Koyanagi. In his decision on motions [*6] (Paper No. 12 in the interference file), the examiner granted the motion and accorded Koyanagi the benefit of the filing date of the Japanese patent application. Upon being accorded benefit, Koyanagi became the "senior party" (page 2 of Paper No. 12 in the interference file). Tytgat in his preliminary statement alleged no date prior to the filing date of the Koyanagi Japanese patent application (Paper No. 3 in the interference file). Accordingly, an order was entered requesting Tytgat to show cause why judgment should not be entered against him (Paper No. 13 in the interference file). When no response was filed, the Board of Patent Interferences entered an award of priority of invention in favor of Koyanagi. Tytgat did not seek judicial review of the award of priority. The "judgment" of the Board of Patent Interferences thus became final. *35 U.S.C. § 135*(a).

Upon resumption of ex parte prosecution, the Tytgat claims corresponding to counts 1-4 (claims 21, 22, 25, and 27) were cancelled. 37 CFR § 1.265. Tytgat then presented amended claims 1, 8, and 9 in their present form (Paper No. 29). The remaining claims on appeal depend directly or indirectly from amended claim 1. [*7] The examiner followed with the final rejection (Paper No. 30) from which this appeal (Paper No. 31) was taken.

The rationale used by the examiner to reject the claims on appeal is not entirely clear. The examiner seemingly has held that there is no patentable distinction between the subject matter of the "lost" counts and the subject matter of the claims on appeal. The examiner's expressed rejection is said to be based, inter alia, on the "judicial doctrine." The examiner apparently believes that the "doctrine" holds that a party who loses an interference is not entitled to a patent to the subject matter of a "lost" count or subject matter which is not "patentably distinct" from the lost count even where the losing applicant is entitled to a foreign priority date which antedates the U.S. filing date of the winning party. *In re Walker, 213 F.2d 332, 102 USPQ 79 (CCPA 1954)* (see point (1), *213 F.2d at 335, 102 USPQ at 82)* and *In re Normann, 150 F.2d 708, 710, 66 USPQ 308, 310 (CCPA 1945).* The examiner acknowledged *In re McKellin, 529 F.2d*

*1324, 188 USPQ 428 (CCPA 1976).* The examiner apparently found McKellin inapplicable because he did not base his rejection [*8] on § 103.

Opinion

1. The Subject Matter of the Claims on Appeal Is not Patentably Distinct from the Subject Matter of the Lost Counts

We will initially discuss the rationale for our conclusion that the subject matter of the claims on appeal is not patentably distinct from the subject matter of the lost counts. We do so because if there is patentable distinctness, there would be no need to discuss the basis upon which the "lost" counts are used to refuse a patent to Tytgat containing the claims on appeal.

The subject matter of claim 1 on appeal differs from the subject matter of the "lost" counts in that it calls for exposing the inner surfaces of a polymerization reactor to an alkali metal iodide prior to charging the vinyl chloride for polymerization. The "lost" counts call for adding an alkali metal iodide to a polymerization mixture. We do not believe the noted difference renders the subject matter on appeal patentably distinct from the subject matter of the "lost counts.

Aruga discloses the use of an oxalic acid build-up inhibitor to prevent build-up in a reactor for polymerizing vinyl chloride. The build-up inhibitor may be added to the polymerization system [*9] (as in the case of the "lost" counts) or it may be coated on the inside wall or stirrer blade of the polymerization reactor in advance of polymerization (as in the case of the claims on appeal) or both procedures may be used. See e.g., col. 1, lines 60-68 and compare claims 2, 3, and 4 (col. 11). Various examples of Aruga illustrate the different procedures for adding the build-up inhibitor to the polymerization system.

Inasmuch as Aruga discloses that a build-up inhibitor may be used before polymerization, during polymerization, or both, we believe that there is no patentable distinction between the use of iodine build-up inhibitor before polymerization, during polymerization, or both. Accordingly, we agree with the examiner that there is no patentable distinction between the subject matter of the "lost" counts (iodine inhibitor used during polymerization) and the subject matter of the claims on appeal (iodide inhibitor used before polymerization).

Except for claims 9 and 10, appellant has not singled out any claim as being patentable apart from claim 1. Accordingly, claims 8, 11-17, 19, and 20 stand or fall with claim 1.

Claim 9 calls for purging the inner surfaces [*10] of the reactor with an aqueous solution containing the iodide build-up inhibitor. The meaning of "purging" is discussed on page 7 of the specification which is quoted, supra. By purging, Tytgat treats the surface. Aruga procedurally describes the same thing in Example 29. Claim 10 calls for adding the iodide build-up inhibitor to the water used as the aqueous phase during polymerization. Aruga also describes adding a build-up inhibitor to the aqueous phase during polymerization. See Example 30. We believe Aruga provides ample basis for concluding that the subject matter of claims 9 and 10 and the subject matter of the "lost" counts are not patentably distinct.

We hold that if a patent containing the claims on appeal is issued to Tytgat, those claims and at least claims 1, 2, 3, and 9 of Koyanagi would define a single inventive concept (i.e., would not be patentably distinct). Thus, it is our view that if a patent is issued to Tytgat containing the claims on appeal, two patents claiming patentably indistinct inventions will have been issued.

In reaching our conclusion that the claimed subject matter and the subject matter of the "lost" counts are not patentably distinct, [*11] we have not overlooked the copy of the summary of Japanese Patent Application 76/85716 submitted by Tytgat. According to Tytgat, that summary discloses the use of an iodide build-up inhibitor on the surfaces of a polymerization reactor prior to polymerization. Tytgat reasons that the second Koyanagi Japanese patent application is evidence that the method claimed here and the method of the "lost" counts must be patentably distinct.

We disagree. Initially, we do not know if the patent law of Japan would permit or preclude Koyanagi from obtaining a second patent to the same inventive concept. We do know that with a terminal disclaimer Koyanagi might do so in this country. In any event, we do not know whether Koyanagi was aware of Aruga at the time he filed the Japanese priority application mentioned in his patent. Compare *In re Kleinman, 488 F.2d 1389, 179 USPQ 244 (CCPA 1973).*

2. It Is Proper to Rely on the "Lost" Counts to Preclude Issuing a Patent to Tytgat

We believe that it is entirely proper to rely on the "lost" counts to reject the claims on appeal. This is true, in our opinion, notwithstanding the decision in McKellin.

I

There are four opinions in **[*12]** McKellin. According to the plurality opinion of the late Judge Lane, the McKellin rejection was based on *35 U.S.C. § 103.* That § 103 rejection was reversed. The examiner here has not relied on *35 U.S.C. 103.* We likewise do not rely on § 103. Rather, our rationale is more like the rationale of point (1) of Walker, supra.

We think it most unlikely that Congress could have intended for two patents to be issued to different parties for a single inventive concept. Thus, we think it unlikely that Congress could have intended for a patent to be issued to Tytgat under the circumstances present here. To the extent that McKellin is otherwise, we respectfully ask the U.S. Court of Appeals for the Federal Circuit to reexamine McKellin in light of the rationale advanced herein. We submit that rationale was not discussed in the McKellin opinion. We respectfully criticize and ask reconsideration of the result (but not necessarily the precise holding) in McKellin in the same spirit and with the same deference expressed by U.S. District Judge Frank G. Theis in *Long v. Citizen's Bank and Trust Co. of Manhattan, 563 F. Supp. 1203, 1211 (D.Kan. 1983):*

This **[*13]** Court now embarks on a very delicate area of judicial holding, that is, a respectful critique of appellate of superior court opinions. It is a tender trap for lower court judges--a sort of Catch 22 situation, to adopt a phrase from a recent novel. In undertaking such a respectful critique, a trial judge may garner ill-will from his statutorily superior brethren on the one hand, and on the other, receive little credit for his intellectual or legal expertise. However, several tenets that this Court believes to be immutably moral and correct compel such a critique under the facts and circumstances of this case. The first immutable tenet is that judicial opinions at any level, including the Supreme Court level, may be less than clear, logical, precise, and well-written in the literary expression sense, in laying down precedential opinions for the public, the lawyers, and other judges alike. The second immutable tenet is the solemn duty of all lawyers, and especially of those lawyers working as judges and law professors, to perfect the law, to strive toward achieving that idealistic ideal of justice, and to define as precisely as possible the principles on which justice may be attained **[*14]** in the decisional process. The duties represented by this second tenet are often met most satisfactorily by pointing out an ambiguity, an omission, or a misconception in a written opinion that form a part of the stare decisis fabric.

II

In support of our rationale that Congress did not intend for two patents to be issued to different parties for the same patentable invention, we note that Congress has provided that the Commissioner may declare an interference when two applications or an application and a patent interfere. Two applications or an application and a patent interfere when both are claiming the same patentable invention. The claims may be (1) identical, (2) different and overlapping in scope, or (3) different and mutually exclusive in scope. *Aelony v. Arni, 547 F.2d 566, 192 USPQ 486 (CCPA 1977).* See also *Case v. CPC International, Inc., 730 F.2d 745, 221 USPQ 196 (Fed. Cir. 1984),* cert. denied, *105 S.Ct. 223 (1984).*

We think it necessarily follows (unless we have erred on the issue of lack of patentable distinctness) that if the judgment involving the "lost" counts of the Tytgat/Koyanagi interference cannot be used to reject the claims on appeal,

[*15] a second interference will have to be declared between those claims and the claims of the Koyanagi patent.

A second interference was declared between McKellin and Maltha after the decision by the CCPA in McKellin. n1 McKellin ultimately prevailed in the second interference because Maltha--the senior party--conceded priority. We do not know why Maltha conceded priority. Perhaps Maltha believed McKellin (who made his invention in the U.S.) could prove priority of invention or perhaps Maltha simply lost interest or lacked funds. Likewise, we do not know why Maltha did not raise an estoppel issue in the second McKellin/Maltha interference. In any event, the claims which Maltha thought he had won in the first interference were taken away from him in the second interference by the same party he had earlier defeated!

n1 In the event of an appeal and to clarify what evidence we have considered, we will note that we have considered the file of the application on appeal, the file of the Koyanagi patent, and the files of the interferences between Tytgat and Koyanagi (No. 100,649) and McKellin and Maltha (Nos. 97,429 and 100,305).

We do not think Congress could have intended [*16] that a winning party be subjected to repeated interferences with a losing party simply because the losing party redefines the same patentable invention with different words so as to avoid the judgment in the first interference. If a second interference is declared in this case and Tytgat does not prevail, all he would need to do to "carry on" is amend the claims again and attempt to hide behind his § 119 claim for priority. How many times could he repeat the scenario? We submit indefinitely or at least enough times to test the patience, will, and financial resources of Koyanagi.We do not think Congress could have intended such a result.

III

Apart from Congressional intent, we believe that as a matter of sound judicial policy, a patent applicant should not have "repeated bites at the apple" in interference cases. *Burson v. Carmichael, 731 F.2d 849, 854, 221 USPQ 664, 667 (Fed. Cir. 1984).* This sound judicial policy (which may have been what the examiner referred to as the "judicial doctrine") is based on the general principles of res judicata and/or estoppel.

If Tytgat felt that his best proofs were within the scope of the claims on appeal, as opposed to original counts [*17] 1-4, he could have moved during the first interference to broaden the counts to include within their scope the subject matter of original counts 1-4 and the subject matter of the claims on appeal. *Wheelock v. Wolinski, 175 USPQ 216* (Comm'r.Pat. 1963); *Kondo v. Martel, 220 USPQ 47, 49 (Bd.Pat.Int. 1983)* (see headnote 5); Manual of Patent Examining Procedure, § 1101.02(B) (5th Ed., Aug. 1983). Had Tytgat done so, the question of who is entitled to a patent to the single inventive concept defined by the combined subject matter of counts 1-4 and the claims on appeal n2 could have been resolved in the Tytgat/Koyangi interference. Compare *In re Bandel, 348 F.2d 563, 146 USPQ 389 (CCPA 1965); In re Derleth, 118 F.2d 566, 49 USPQ 84 (CCPA 1941).* Nothing in the PTO rules would have precluded Tytgat from establishing--if he could--priority of invention in the Tytgat/Koyanagi interference of the presently claimed subject matter vis-a-vis the subject matter which Koyanagi won in that interference. Alternatively, Tytgat could have suggested a "phantom" n3 count directed to the two patentably indistinct inventions defined by the claims now on appeal and [*18] the claims of the Koyanagi patent. Had Tytgat filed a motion to substitute a "phantom" count for Original counts 1-4, he also would have amended his application to include the claims on appeal. Those claims would have been designated to correspond to the phantom counts. The Koyanagi claims would also have been designated to correspond to the phantom counts. The Tytgat claims and the Koyanagi claims would have covered mutually exclusive subject matter. However, since both sets of claims define the same patentable invention, an interference-in-fact would have existed upon which a priority determination could have been made. *Aelony v. Arni, supra.* We do not believe McKellin must be "overruled" to reach the result we think is correct. We have not based out rejection on § 103. Rather, we have based the rejection on the judgment in the Tytgat/Koyanagi interference. Our basis is similar to the basis of point (1) of Walker. n4

n2 Had Tytgat filed an appropriate motion he also would have amended his application to include claims

corresponding exactly to the broader counts. The Koyanagi claims would also have been designated to correspond to the counts notwithstanding the fact those claims would have been narrower than the counts. MPEP § 1101.02(B), supra. Had Tytgat won, he would have been entitled to the broader claims.

n3 For a discussion of "phantom" counts, see Modance, "Modified" Interference Practice and "Phantom Counts," *52 J. Pat. Off. Soc'y. 207, 210-212 (1970).*

n4 We note that Judge Miller's dissent in McKellin suggests that Walker and Normann were overruled by McKellin. The plurality opinion and the two concurring opinions do not indicate that walker and Normann were overruled. We believe the plurality opinion and concurring opinions properly declined to discuss Walker, because point (1) of Walker simply was not involved in McKellin. In any event, we will not assume that Walker and Normann were overruled sub silentio. Nor will we assume that they would be overruled upon consideration of the rationale we have advanced in this opinion.

[***19**]

IV

In the dissent (infra), it is alleged that McKellin is on all fours with the present appeal. We disagree. Wile the dissent's view is superficially plausible, it will not withstand penetrating analysis. The issue here and the issue is McKellin are different. In McKellin, the CCPA characterized the issue as follows, *529 F.2d at 1325, 188 USPQ at 430:*

The sole issue on appeal is whether claims may be rejected under *35 U.S.C. 103* on the ground that a losing party to an interference is not entitled to claims which are asserted to be obvious variations of the invention defined in the counts, when section 102(g) and interference estoppel are not applicable (emphasis added).
The issue here is not obviousness under *35 U.S.C. § 103* or so-called interference estoppel. Rather, we rely (and we believe the examiner intended to rely) on the more general principles of res judicata and collateral estoppel wherein a judgment previously rendered bars consideration of questions of fact or mixed questions of fact and law which were, or should have been, resolved in earlier litigation. *In re Pritchard, 463 F.2d 1359, 1364, 175 USPQ 17, 21 (CCPA 1972).*

Consistent with [***20**] the general principles of res judicata and estoppel announced in Pritchard, sound judicial and administrative policy dictates that an interference should settle all issues which are decided or which could have been decided. *Blackford v. Wilder, 28 App.D.C. 535, 542, 550, 1907 Dec.Comm'r.Pat. 491, 496, 501 (1907); Daniels v. Coe, 73 App.D.C. 54, 56, 116 F.2d 941, 943, 47 USPQ 203, 205 (1940);* and *U.S. Rubber Co. v. Coe, 79 U.S. App.D.C. 305, 146 F.2d 315, 64 USPQ 100 (1943).* Moreover, when an applicant loses an interference, the applicant is not entitled to a patent containing claims corresponding to the count or claims which are not patentably distinct from the count. *Smith v. Watson, 95 U.S. App.D.C. 52, 218 F.2d 863, 104 USPQ 150 (1955).* See also *In re Fenn, 315 F.2d 949, 137 USPQ 367 (CCPA 1963).*

Since we have not relied on section 103 to reject Tytgat's claims, it necessarily follows that McKellin is not on all fours and does not control here.

The dissent also argues that res judicata is not appropriate here. Relying on numerous cases where a res judicata rejection was made in an application based on a prior ex parte "judgment," [***21**] the dissent overlooks the critical difference between an ex parte judgment and an inter partes judgment. The public interest permits an applicant to avoid a prior ex parte judgment if on a different record that applicant can establish a right to a patent under the Patent Statute. The rationale in support of not always using a prior ex parte judgment to subsequently defeat an applicant in a second ex parte proceeding is set forth in the various opinions of *In re Herr, 377 F.2d 610, 153 USPQ 548 (CCPA 1967).* Ex parte res judicata rejections based on a prior ex parte judgment have been limited to those cases where the issues in the ex parte proceeding leading to the judgment and the issues in the subsequent ex parte proceeding are the same. See e.g., *In re Katz, 467 F.2d 939, 167 USPQ 487 (CCPA 1970).* The public as a whole benefits from this policy. No particular member of the public is harmed by the policy. When a res judicata or estoppel rejection is made on the basis of a prior

inter partes judgment, however, an important consideration is the fact that a particular member of the public has already been put to the expense of an interference. If the inter partes judgment **[*22]** can be avoided in subsequent ex parte prosecution by substituting patentably indistinct claims for the claims corresponding to the "lost" count, not much will have been gained by the interference. As we have pointed out above, a second (and possibly a third, fourth . . . and umpteenth) interference may be necessary to finally settle the rights between the parties. No public benefit is obtained by having more than one interference to resolve the patent rights to a single patentable invention.

There is one aspect of the dissent with which we generally agree, viz., the law should be settled. We also agree that orderly administration of justice dictates that we follow the letter and the spirit of precedent of our appellate court. However, as Judge Theis suggested in *Long v. Citizen's Bank and Trust Co., supra,* there is nothing wrong on appropriate occasions in suggesting to an appellate court that a matter be looked at again from a different point of view.

If the Commissioner of Patents had not asked the Court of Customs and Patent Appeals to reexamine In re Palmquist n5 the law might be different today; In re Palmquist was overruled by In re Foster. **[*23]** n6 Part of In re Risse n7 was overruled sua sponte by the Court of Customs and Patent Appeals in In re Smith. n8 As of 1978, our Supreme Court had overruled at least 168 of its own cases. The Constitution of the United States Analysis and Interpretation, S. Doc. 92-82, 92nd Cong., 2d Sess. 1789-1797 (1973); S. Doc. 96-26, 96th Cong., 1st Sess. A294-295 (Supplement 1978). We do not ask our appellate court to overrule the precise holding of McKellin. Rather, we ask the Federal Circuit to reexamine the result reached in McKellin on a rationale not there considered. In light of Anglo-American jurisprudence which permits courts on appropriate, albeit rare, occasions to reexamine cases, we see nothing wrong in our approach.

n5 *In re Palmquist, 319 F.2d 552, 138 USPQ 234 (CCPA 1963).*

n6 *In re Foster, 343 F.2d 980, 145 USPQ 166 (CCPA 1965).*

n7 *In re Risse, 378 F.2d 948, 154 USPQ 1 (1967).*

n8 *In re Smith, 458 F.2d 1389, 173 USPQ 679 (CCPA 1972).*

Decision

For the reasons advanced herein, the decision of the examiner rejecting the claims on appeal is affirmed. Since we have developed what we think may have been a rationale different from the **[*24]** examiner, we choose to designate our affirmance as a new ground of rejection under 37 CFR § 1.196(b). If he desires, Tytgat may place additional evidence in the record to attempt to show that the claimed invention and the invention of the "lost" counts are patentably distinct.

Any request for reconsideration or modification of this decision by the Board of Appeals based upon the same record must be filed within thirty days from the date hereof. 37 CFR § 1.197.

With respect to the new rejection under 37 CFR § 1.196(b), should appellants elect the alternative option under that rule to prosecute further before the primary examiner by way of amendment or showing of facts, or both, not previously of record, a shortened statutory period for making such response is hereby set to expire one month from the date of this decision.

AFFIRMED

37 CFR 1.196(b)

**DISSENTBY:** BLECH

**DISSENT:**

Blech, Examiner-in-Chief, dissenting.

I respectfully disagree with the holding of the majority. I would reverse the Examiner's rejection of the claims before us, no matter on what basis it is postulated.

The majority apparently realizes and recognizes that McKellin dictates a reversal of the rejection, **[*25]** but rationalizes that by not basing it on *35 USC 103,* but, rather, denominating it as being founded on res judicata the rejection can be sustained and on this ground affirms the Examiner's rejection, albeit not for the reasons as given by him.

Preliminarily, I note that such an approach by the majority is contra to an established desideratum calling for certainty in the law and which should not be disturbed, absent compelling reasons which I do not find to be present here. Clearly, the facts of this case are on all fours with those that prevailed in McKellin and which would compel a reversal of the rejection. An applicant should be able to rely on the precedent established by McKellin as applying to all factually analogous situations. The majority, however, will force appellants herein to endure inconvenience and expense to assert their rights which they are entitled to.

Our reviewing court in McKellin has interpreted the law applicable to a factual situation as present herein as necessitating a reversal of a rejection of claims drawn to a different embodiment than defined by "lost" counts of an interference even though not patentably distinct therefrom. A different **[*26]** result should not be reached by nominally denominating the rejection as based on a variant rationale, i.e. the judicially created doctrine of res judicata, or "the judgment in the Tygat Koyanagi/interference" which, as I understand it, is collateral estoppel, also a form of res judicata, and both of which, in my view, are inapplicable herein. Otherwise, semantics would prevail over substance. This Board should be bound by McKellin and not place a burden on appellants by criticizing this decision and trying to impose its view upon the court by giving it "repeated bites at the apple," a practice equally not condoned in interference cases.

The majority urges that anomalous, unacceptable and congressionally unintended results would flow from interpreting the law as in McKellin. The court, however, was aware of this, yet felt that any change therein must come by legislation, not by judicial fiat. But the majority, contrary thereto, attempts to impose its interpretation and understanding of the law upon the facts of this case by applying to it just that, i.e. the judicially created doctrine of res judicata. Clearly such is unwarranted and, in my opinion, as discussed **[*27]** and developed below, in any event, is not a proper basis for a rejection.

In in *re Hellbaum, 54 CCPA, 1051, 371 F.2d 1022, 152 USPQ 571,* the court in holding that a prior determination of unpatentability of an admixture of sugar and fluorine salt is not res judicata to the issue of whether or not fluorine coated sugar crystals are obvious stated at p. 572:

Res judicata requires, inter alia, a showing of an identity of the issues presented for adjudication and the issues previously decided. *In re Szwarc, 50 CCPA 1571, 319 F.2d 277, 138 USPQ 208, In re Fried, 50 CCPA 954, 312 F.2d 930, 136 USPQ 429* (original emphasis).

Res judicata is also discussed by the court in footnote 2 of *In re Oelrich et al, 666 F.2d 578 (1981) 212 USPQ 323,* to wit:

. . . res judicata does not have its usual impact when considering ex parte patent appeals; the public interest in granting valid patents outweighs the public interest underlying collateral estoppel and res judicata, particularly where the issue presented is not substantially identical to that previously decided. *In re Russell, 58 CCPA 1081, 1083, 439 F.2d 1228, 1230, 169 USPQ 426, 428 (1971); In re Craig, 56 CCPA 1438,* **[*28]** *1441-42, 411 F.2d 1333, 1335-36, 162 USPQ 157, 159 (1969).*

The court in *In re Szwarc, 50 CCPA 1571, 319 F.2d 277, 138 USPQ 208,* in characterizing res judicata quotes at

length from the Supreme Court decision of *Commissioner v. Sunnen, 333 U.S. 591, 77 USPQ 19,* viz.

It is first necessary to understand something of the recognized meaning and scope of res judicata, a doctrine judicial in origin. The general rule of res judicata applies to repetitious suits involving the same cause of action. It rests upon considerations of economy of judicial time and public policy favoring the establishment of certainty in legal relations. The rule provides that when a court of competent jurisdiction has entered a final judgment on the merits of a cause of action, the parties to the suit and their privies are thereafter bound "not only as to every matter which was offered and received to sustain or defeat the claim or demand, but as to any other admissible matter which might have been offered for that purpose." * * *

But where the second action between the same parties is upon a different cause or demand, the principle of res judicata is applied much more narrowly. In this situation, **[*29]** the judgment in the prior action operates as an estoppel, not as to matters which might have been litigated and determined, but "only as to those matters in issue or points controverted, upon the determination of which the finding or verdict was rendered." Cromwell v. County of Sac, supra, 353. And see *Russell v. Place, 94 U.S. 606; Southern Pacific R. Co. v. United States, 168 U.S. 1, 48; Mercoid Corp. v. Mid-Continent Co., 320 U.S. 661, 671, 60 USPQ 21, 26-27.* Since the cause of action involved in the second proceeding is not swallowed by the judgment in the prior suit, the parties are free to litigate points which were not at issue in the first proceeding, even though such points might have been tendered and decided at that time. But matters which were actually litigated and determined in the first proceeding cannot later be relitigated. Once a party has fought out a matter, in litigation with the other party, he cannot later renew that duel. In this sense, res judicata is usually and more accurately referred to as estoppel by judgment, or collateral estoppel. * * *

It can thus be seen that for a holding of res judicata to apply in patent prosecution an identity, or **[*30]** substantial identity, of issues is required. Such is not seen to be present here where the claimed mode of using the "build-up" inhibitor of the claims (1) is not disclosed by Koyanagi, (2) was not an issue in the interference, nor (3) could have been made an issue of the interference, and (4) is urged by appellants to constitute a patentably distinct embodiment.

If res judicata is construed as meaning "estoppel by judgment" or "collateral estoppel," as it is also interpreted by the court in Szwarc, these same reasons preclude its applicability to the facts of this case.

*In re Risse, 54 CCPA 1495, 378 F.2d 945, 154 USPQ, 1,* and *In re Wilding, 535 F.2d 631, 190 USPQ 59,* appear to be the leading cases on the doctrine of interference or collateral estoppel, but I do not find them to dictate as establishing a burden on an applicant in interference with a patent, such as is the case here, to divine, contrary to his belief, that there is no patentable distinction between that part of his disclosure which is not common to the patent claims and patent disclosure and to move for the substitution or addition of broader counts. Appellants believe, and so urge, that the appealed **[*31]** claims patentably distinguish over the "lost" counts. They should not be penalized for so believing even though the majority has ruled, correctly or incorrectly, as may be decided by our reviewing court and subject to justifiable and reasonable differences of opinion, that the claimed process is an obvious variant of the process as defined by the "lost" counts. Reasonable men can differ whether prior passivation of the walls of a reactor with an alkali metal iodide as "build-up" inhibitor is an obvious variant vis-a-vis introducing this "build-up" inhibitor into a polymerization mixture in the reactor, as in the "lost" count. It could not necessarily have been foreseen that such prior passivation which does not require the presence of the "build-up" inhibitor during the polymerization will be effective. Aruga does not necessarily make this an expected result inasmuch as this patent relates to a completely different "build-up" inhibitor which may or may not function in the same manner as an alkali metal iodide.

Further, I also like to point out that Walker relied upon by the majority, quite evidently no longer represents viable precedent, it, in my view, sub silentio, **[*32]** having been overruled by McKellin, as is specifically alluded to by Judge Miller's dissent in McKellin (note p. 444). I also believe that in order to arrive at the result desired by the majority McKellin must, in fact, be overruled.

**Legal Topics:**

LexisNexis

LEXSTAT 37 CFR § 41.127



*** THIS SECTION IS CURRENT THROUGH THE APRIL 1, 2009 ISSUE OF ***
*** THE FEDERAL REGISTER ***

TITLE 37 -- PATENTS, TRADEMARKS, AND COPYRIGHTS
CHAPTER I -- UNITED STATES PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE
SUBCHAPTER A -- GENERAL
PART 41 -- PRACTICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
SUBPART D -- CONTESTED CASES

**Go to the CFR Archive Directory**

*37 CFR 41.127*

§ 41.127 Judgment.

(a) Effect within Office -- (1) Estoppel. A judgment disposes of all issues that were, or by motion could have properly been, raised and decided. A losing party who could have properly moved for relief on an issue, but did not so move, may not take action in the Office after the judgment that is inconsistent with that party's failure to move, except that a losing party shall not be estopped with respect to any contested subject matter for which that party was awarded a favorable judgment.

(2) Final disposal of claim. Adverse judgment against a claim is a final action of the Office requiring no further action by the Office to dispose of the claim permanently.

(b) Request for adverse judgment. A party may at any time in the proceeding request judgment against itself. Actions construed to be a request for adverse judgment include:

(1) Abandonment of an involved application such that the party no longer has an application or patent involved in the proceeding,

(2) Cancellation or disclaiming of a claim such that the party no longer has a claim involved in the proceeding,

(3) Concession of priority or unpatentability of the contested subject matter, and

(4) Abandonment of the contest.

(c) Recommendation. The judgment may include a recommendation for further action by the examiner or by the Director. If the Board recommends rejection of a claim of an involved application, the examiner must enter and maintain the recommended rejection unless an amendment or showing of facts not previously of record is filed which,

in the opinion of the examiner, overcomes the recommended rejection.

(d) Rehearing. A party dissatisfied with the judgment may file a request for rehearing within 30 days of the entry of the judgment. The request must specifically identify all matters the party believes to have been misapprehended or overlooked, and the place where the matter was previously addressed in a motion, opposition, or reply.

**HISTORY:** *[69 FR 49960, 50003,* Aug. 12, 2004; *69 FR 58260,* Sept. 30, 2004]

**AUTHORITY:** AUTHORITY NOTE APPLICABLE TO ENTIRE PART:
*35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 41, 134, 135.*

**NOTES:** [EFFECTIVE DATE NOTE: *69 FR 49960, 50003,* Aug. 12, 2004, added Part 41, effective Sept. 13, 2004; *69 FR 58260,* Sept. 30, 2004, revised paragraph (d), effective Sept. 30, 2004.]

NOTES APPLICABLE TO ENTIRE CHAPTER:
EDITORIAL NOTE: Chapter I -- Patent and Trademark Office, Department of Commerce, Subchapter A -- General, contains patent and trademark regulations. Subchapter A has been restructured to allow parts pertaining to patent regulations and trademark regulations to be grouped separately.

NOTES APPLICABLE TO ENTIRE SUBCHAPTER:
[PUBLISHER'S NOTE: "The parts in chapter I, subchapter A are regrouped according to subject matter. All parts pertaining to patents--parts 1 and 5--appear sequentially. All parts pertaining to trademarks--parts 2 and 6--follow, also in sequence. Part 3 which pertains to both patents and trademarks follows part 1."]

NOTES APPLICABLE TO ENTIRE PART:
[PUBLISHER'S NOTE: The authority citation for Part 41 was revised at *73 FR 32938, 32972,* June 10, 2008, effective Dec. 10, 2008. *73 FR 74972,* Dec. 10, 2008, provides: "The effective date for the final rule published at *73 FR 32938,* June 10, 2008, is delayed, pending completion of OMB review of the proposed information collection under the PRA. The Office will issue a subsequent notice identifying a revised effective date on which the final rule shall apply." For the convenience of the user, the authority citation which will go into effect at a later time, has been set out below:
*35 U.S.C. 2(b)(2), 3(a)(2)(A), 21, 23, 32, 132, 133, 134, 135, 306,* and *315.*]
[PUBLISHER'S NOTE: For Federal Register citations concerning Part 41 Interpretations, see: *73 FR 70282,* Nov. 20, 2008.]

329 words

LEXSEE 55 U.S.P.Q.2D 1537



UNITED STATES PATENTS QUARTERLY

Ex parte Kimura

Appeal No. 1999-1918

U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences

55 U.S.P.Q.2D (BNA) 1537

Decided July 13, 2000

**CASE HISTORY and DISPOSITION:** Patent application of Fumio Kimura, Takahiro Haga, Nobuyuki Sakashita, Shigeo Murai, Yuji Nakamura, and Sooichi Honzawa, serial no. 08/291,822. n1 Applicants appeal from rejection of application claim 13. Rejection affirmed on new ground under 37 C.F.R. Section 1.196(b).

n1 Application filed 17 August 1994 to reissue U.S. Patent 5,139,565. The real party in interest is Ishihara Sangyo Kaisha, Ltd. The patent issued 18 August 1992, based on application 07/658,246, filed 20 February 1991. Applicants claim priority under 35 U.S.C. Section 119 based on Japanese patent application 2-39063, filed 20 February 1990.

[Editor's Note: The Board of Patent Appeals and Interferences states that this decision is not binding precedent of the board.]

**HEADNOTES:**
PATENTS

[**1H] Practice and procedure in Patent and Trademark Office -- Prosecution -- Rules and rules practice (110.0905)

Practice and procedure in Patent and Trademark Office -- Interference -- Estoppel (110.1704)

Rejection based on estoppel arising out of interference, and rejection based on recapture, are grounded on different rationales, and examiner therefore should not attempt to create recapture rejection based on subject matter lost during interference; rather, proper rejection is one based on 37 C.F.R. Section 1.658(c), dealing with estoppel.

[**2H] Practice and procedure in Patent and Trademark Office -- Prosecution -- Rules and rules practice (110.0905)

Practice and procedure in Patent and Trademark Office -- Interference -- Estoppel (110.1704)

Patent applicants' claim, if separately patentable from counts "lost" in interference, must be rejected based on estoppel under 37 C.F.R. Section 1.658(c) for failure to take action during interference to place subject matter of claim in issue, since patent issued to applicants' opponent in interference describes subject matter of applicants' present claim, and since applicants failed to move to add reissue application and new count to interference, or to move, under 37 C.F.R. Section 1.633(e), to have second interference declared involving allegedly separately patentable subject matter of applicants' claim; alternatively, if claim defines invention which is not separately patentable from subject matter of lost counts, then claim is unpatentable to applicants based on proposition that party who has lost in interference is not entitled to claim invention which is not separately patentable from lost count.

[**3H] Practice and procedure in Patent and Trademark Office -- Interference -- Pleadings and submissions (110.1706)

Practice and procedure in Patent and Trademark Office -- Interference -- Estoppel (110.1721)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Settlement agreements; consent decrees (410.43)

Settlement agreement stating that assignee of prevailing party in patent interference "will not claim" subject matter of claim at issue in present application for patent does not preclude rejection of that claim based on estoppel under 37 C.F.R. Section 1.658(c), since mere fact that applicants' opponent in interference did not claim subject matter of application claim is not statement that opponent believes applicants are entitled to claim, since Rule 1.658(c) operates independently from views of winning party in interference, and since acts of Board of Patent Appeals and Interferences in receiving and storing timely filed settlement agreements are ministerial only, and board neither enforces nor reviews appropriateness of terms in settlement agreements.

**CLASS-NO:** 110.0905, 110.1704, 110.1706, 110.1721, 410.43

**COUNSEL:** Richard D. Kelly, of Oblon, Spivak, McClelland, Maier & Neustadt, Arlington, Va., for appellants.

**JUDGES:** Before Smith, administrative patent judge, McKelvey, senior administrative patent judge, and Robinson, administrative patent judge.

**OPINIONBY:** McKelvey, J.

**OPINION:**

Decision on appeal under *35 U.S.C. Section 134* The appeal is from a decision of the Primary Examiner rejecting claim 13. The appeal raises an issue of estoppel under 37 CFR Section 1.658(c) [Rule 658(c)].

We affirm, but designate our affirmance as a new ground of rejection under 37 CFR Section 1.196(b).

A. Findings of fact

The record supports the following findings by a preponderance of the evidence.

Reissue application on appeal 1. The application on appeal seeks to reissue U.S. Patent 5,139,565, granted 18 August 1992, based on application 07/658,246, filed 20 February 1991.

2. The application contains one claim. Claim 13 reads as follows: **[*1539]**

A method for controlling weeds in a corn field which comprises applying a herbicidally effective amount of a substitute pyridinesulfonamide compound or salt thereof having the following [structural] formula: (Source Materials are available by calling BNA PLUS, (800) 452-7773 nationwide, or (202) 452-4132 in Washington, D.C.)

wherein R3 is hydrogen or methyl.

3. The specification describes numerous compounds. One compound is N-[4,6-dimethoxypyrimidin-2-yl)-aminocarbonyl]-3-(N'-methyl-N'-methylsulfonylamin o)-2-pyridinesulfonamide (col. 9, Example 1).

4. Applicants have designated the compound as Compound 1 and it has the structural formula: (Source Materials are available by calling BNA PLUS, (800) 452-7773 nationwide, or (202) 452-4132 in Washington, D.C.)

5. Compound 1 is the compound of Claim 13 when R3 is hydrogen.

6. Compound 1 is said to be a selective herbicide, killing most weeds. According to applicants, Compound 1 has a herbicidal rating of 5 out of 10 with respect to corn (col. 16, Table 3). Ratings are based on a scale of 1 to 10. A rating of 1 indicates no effect on a plant (col. 16, lines 55-56). A rating of 10 means a plant is completely killed (col. 16, lines 54-55). Thus, while Compound 1 has some negative effect on corn, it will selectively kill weeds in a corn field.

7. The specification also describes N-[(4,6-dimethoxypyrimidin-2-yl)-aminocarbonyl]-3-(N'-methyl-N'-methylsulfonylami no)-6-methyl-2-pyridinesulfonamide (col. 10, Example 2).

8. Applicants have designated the compound as Compound 12 and it has the structural formula: (Source Materials are available by calling BNA PLUS, (800) 452-7773 nationwide, or (202) 452-4132 in Washington, D.C.)

9. Compound 12 is the compound of claim 13 when R3 is methyl in the 6-position.

10. Compound 12 is also said to be a selective herbicide, killing most weeds. According to applicants, Compound 12 has a herbicidal rating of 3 out of 10 with respect to corn (col. 17, Table 3, cont'd). Thus, Compound 12 would appear to have less of an impact on corn than Compound 1, while killing essentially all weeds in a corn field.

Interference 103,406 11. There came a time when Interference 103,406 was declared on 15 September 1995, involving:

(1) applicants' U.S. Patent 5,139,565 (the patent here sought to be reissued), having a priority benefit date of 20 February 1990, and (2) Kehne application 07/859,513, based on a PCT application and having a *35 U.S.C. Section 102*(e) date of 8 June 1992, and a priority benefit date of 10 January 1990.

12. Based on their respective priority dates, Kehne was senior party and applicants were junior party.

13. At the time Interference 103,406 was declared, claim 13 on appeal was pending in the reissue application on appeal.

14. The reissue application on appeal was not involved in the Interference 103,406.

15. The interference involved three counts (Paper 24, Appeal Brief, pages 5-8).

16. Count 1 was (Appeal Brief, pages 5-6) (indentation added): **[*1540]**

A substituted pyridinesulfonamide compound having the formula (I): (Source Materials are available by calling BNA PLUS, (800) 452-7773 nationwide, or (202) 452-4132 in Washington, D.C.)

where

R1 is an alkyl group, a haloalkyl group, an alkoxyalkyl group, the alkyl moieties containing from 1-4 carbon atoms, or a C2-C4 alkenyl group,

R2 is a hydrogen atom, an alkyl group, a haloalkyl group, an alkoxyalkyl group, the alkyl moieties containing from 1-4 carbon atoms, or C2-C4 alkenyl group,

R3 is a hydrogen atom, a halogen atom, an alkyl group, a haloalkyl group, an alkoxy group, an alkylthio group, an alkoxyalkyl group, and alkylamino group or a dialkylamino group, the alkyl moieties containing from 1-4 carbon atoms, and

each of X and Y which are independent from each other, is a halogen atom, an alkyl group, an alkoxy group or a haloalkoxy group, the alkyl moieties containing from 1-4 carbon atoms, or its salt.

17. Count 2 was (Appeal Brief, page 7):

A herbicidal composition comprising a herbicidally effective amount of the substituted pyridinesulfonamide compound of the formula (I) as defined in count 1 or its salt, and an agricultural adjuvant.

18. Count 3 3/4as (Appeal Brief, pages 7-8) (bracketed material added):

A method of combating undesired plants or of regulating the growth of plants comprising applying to the plants, plant seed or a cultivated area a herbicidally or plant-growth regulating effective amount of a compound having the formula (I): (Source Materials are available by calling BNA PLUS, (800) 452-7773 nationwide, or (202) 452-4132 in Washington, D.C.)

where * * *

[R1, R2, R3, and each of X and Y have the same meaning as in Count 1] and its salt.

19. During an interference, a party may file a preliminary motion to add a reissue application to the interference. See 37 CFR Section 1.633(h) and 37 CFR Section 1.637(h).

20. During an interference, a party also may file a preliminary motion to redefine the interference by adding a count. See 37 CFR Section 1.633(c)(1) and 37 CFR Section 1.637(c)(1).

21. When such a preliminary motion seeks to add a count, the moving party is obligated to show that each proposed count defines a separate patentable invention from every other count proposed to remain in the interference. 37 CFR Section 1.637(c)(1)(v). See also 37 CFR Section 1.601(f) (" [w]hen there is more than one count, each count shall define a separate patentable invention."). A party must also propose a claim to be added to its opponent's application if the application does not already contain a suitable claim. 37 CFR Section 1.637(c)(1)(iii).

22. Applicants maintain in this appeal that the subject matter of claim 13 defines a separate patentable invention from the subject matter of the counts of Interference 103,406.

23. During Interference 103,406, applicants did not file (1) a preliminary motion to add their reissue application containing claim 13 and (2) a preliminary motion to redefine the interference by adding a second count to a separate patentable invention, e.g., the subject matter of claim 13 on appeal.

24. During Interference 103,406, had applicants filed a preliminary motion to add their reissue and a preliminary motion to redefine the interference by adding a count directed to the invention of claim 13 on appeal, (1) the preliminary motions would have been granted n2 and (2) Kehne **[*1541]** and applicants could have contested priority on the subject matter of claim 13.

n2 A preliminary motion to add a reissue will be granted only if all new claims in the reissue are to be designated as corresponding to a count. *Winter v. Fujita , 53 USPQ2d 1234* (Bd. Pat. App. & Int. 1999), reconsideration denied , *53 USPQ2d 1478* (Bd. Pat. App. & Int. 1999). Original patent claims 1-9 of applicants' patent corresponded to counts in the interference. New reissue claim 13 would have corresponded to a proposed new count. New reissue claims 10-12 would have corresponded to the original counts or the proposed new count, depending on whether the properties of the compounds of claims 10-12 are deemed to render those compound claims separately patentable from the compounds of Count 1. It appears to be applicants' position in this appeal that the compounds of reissue claims 10-12 possess properties which render those compounds separately patentable from the compounds of Count 1.

25. During an interference, a party also may move to have a second interference declared between an application owned by the party and an opponent's application or patent involved in the interference. 37 CFR Section 1.633(e).

26. In the event the opponent is an applicant, the party is required to show that the opponent applicant describes the invention and, if the opponent applicant does not claim the invention described, propose a claim to be added to the opponent applicant's application. 37 CFR Section 1.637(e)(1)(v) and (vi).

27. On 23 October 1996, applicants filed a motion requesting entry of an adverse judgment in Interference 103,406. See 37 CFR Section 1.662(a).

28. The motion was granted and on 1 November 1996 a judgment was entered against applicants as to each of Counts 1-3.

The settlement agreement 29. We are told by applicants that applicants' assignee (Ishihara Sangyo Kaisha, Ltd.) and Kehne's assignee (Hoechst Schering AgrEvo GmbH) entered into an agreement to settle the interference.

30. Based on docket records at the board, the panel has determined that a settlement agreement was filed on 23 October 1996 (copy of Docket entries attached hereto).

31. The panel has also determined that the parties to #the agreement, consistent with *35 U.S.C. Section 135*(c), requested that the settlement agreement be kept separate from the file of the interference.

32. On 28 October 1996, an order was entered at the board stating (copy of order attached):

The copy of the agreement under *35 U.S.C. 135*(c) filed by Kimura et al on October 23, 1996 is acknowledged. Pursuant to their request, this agreement will be kept separate from the file of the interference as provided in the statute

[i.e., *35 U.S.C. Section 135*(c)].

33. In their appeal brief (Paper 24, page 9, lines 10-11), applicants tell us that the agreement contains a provision to the effect that "AgrEvo [, Kehne's assignee,] will not claim Ishihara's alleged separate patentable invention as presented by Ishihara reissue claim 13." n3

n3 Since a request was made to maintain the settlement agreement separate from the files, we have not considered the agreement and the agreement is not part of the record in this appeal. Consistent with 37 CFR Section 1.56, we will assume that applicants and their counsel have revealed on this record all material in the settlement agreement which might be relevant to the issues on appeal.

34. Applicants go on to state ( id .):

The Board accepted this settlement agreement. Accordingly, there was nothing within the interference which would prevent * * * [applicants] from pursuing a patent on this selection invention of Claim 13 in a separate application, but Claim 13 could not have been properly pursued in * * * [Interference 103,406] as it is a separately patentable invention and the [interference] rules do not allow the addition of a claim to an interference in order to have it designated as not corresponding to the count.

The Kehne patent 35. Following entry of a judgment against applicants in Interference 103,406, a patent was issued to Kehne based on the Kehne application involved in the interference.

36. Thus, on 3 June 1997, U.S. Patent 5,635,451 was granted to Kehne.

37. The Kehne patent describes certain 2-pyridyl-sulfonylureas (col. 1, line 20) which are said to (col. 5, lines 27-29):

have an excellent herbicidal activity against a broad spectrum of economically important monocotyledon and dicotyledon weeds.

38. Kehne also tells us that (col. 6, lines 1-8) (emphasis added):

[a]lthough the compounds according to the invention have an excellent herbicidal **[*1542]** activity against monocotyledon and dicotyledon weeds, crop plants of economically important crops such as, for example, wheat barley, rye, rice, corn , sugarbeet, cotton and soya are only damaged insubstantially or not at all. For these reasons, the present compounds are very highly suitable for selectively controlling undesired plant growth in agricultural productive plantings.

39. Numerous compounds are described by Kehne as falling within the scope of his invention, including "salts" of those compounds (col. 3, lines 1-9).

40. In Table 1 (which runs from col. 9/10 until col. 37/38), Kehne describes 895 specific compounds, two of which are applicants' Compound 1 and Compound 12.

41. Compound 439 (col. 21/22) (1) has the same structural formula as applicants' Compound 1 and (2) is said to have a melting point of 177-178 degrees C. n4

n4 We note that applicants' Compound 1 is said to have a melting point of 181-184 degrees C (col. 10, lines 49-50). We have no idea why applicants and Kehne report different melting points for compounds having the same structural formula. We note that claim 13 does not have a melting point limitation. We also note that the "X" in the ring structure of the formula in Table 1 of Kehne is a misprint and should be a "Z". Compare col. 3, line 15. In Kehne Compound 439, "Z" is CH.

42. Compound 481 (col. 23/24) (1) has the same structural formula as applicants' Compound 12 and (2) is said to have a melting point of 185 degrees C. n5

n5 We note that applicants say the melting point is 162-168 degrees C (col. 12, lines 67-68). We have no idea why applicants and Kehne report different melting points for compounds having the same structural formula. As noted earlier, we note that claim 13 does not have a melting point limitation.

43. Table 5 describes the pre-emergence activity of some of Kehne's compounds, including Compound 439. Kehne appears to use a numerical rating system with numbers from 0 n6 to 5. The higher the rating, the more effective the compound. Compound 439 was rated 5 for all weeds tested.

n6 Note the 0 in Table 6 for Compound 340 with respect to AVSA.

44. Table 6 describes post-emergence activity of some of Kehne's compounds, including Compound 439. Compound 439 was rated 5 for all weeds tested.

45. Kehne also reveals with respect to crop plant tolerability that (col. 48, lines 26-36) (emphasis added):

Four to five weeks after application and standing in a greenhouse, it was determined by means of optical assessment that the compounds according to the invention left dicotyl crops such as, for example, soya, cotton, rape, sugarbeet and potatoes undamaged pre- and post-emergence even at high active compound dosages. Moreover, some substances also spared gramineous crops such as, for example, barley, wheat rye, sorghum millet, corn and rice. The compounds of formula (I) thus have a high selectivity when used for controlling undesired plant growth in agricultural crops.

46. Kehne describes the subject matter of applicants' claim 13. n7

n7 Kehne also describes the subject matter of applicants' now cancelled new reissue claims 10-12. Claim 11 was directed to Compound 1 and its salts. Claim 12 was directed to Compound 12 and its salts. Claim 10 was directed to both Compound 1 and Compound 12 and their salts.

Applicants' Rule 132 declarations 47. During post-interference prosecution of the reissue application, applicants presented (1) a first declaration of Nobuyuki Sakashita, dated 21 March 1997 (Paper 16), and (2) a second declaration of Mr. Sakashita, dated 2 October 1997 (Paper 19).

48. Data in the declarations, said to be based on experimental work, shows the herbicidal effect of Compounds 1 and 12, as well as other compounds falling within the scope of the disclosure of Kehne and Count 1.

49. Based on the declarations, applicants tell us that Compounds 1 and 12 "provide surprising improvements not only in the killing of weeds * * * but also with respect to safety to * * * corn in the corn field" (Appeal Brief, page 8, last paragraph). In short, applicants maintain that the declarations provide evidence that the "narrow" subject matter of claim 13 on appeal is separately patentable from the "broad" subject matter of Counts 1-3 of Interference 103,406.

The examiner's rejections 50. The examiner's final rejection is not a model of clarity.

51. As best we can tell, the examiner appears to have entered three rejections.

52. In a first rejection, Claim 13 appears to have been rejected as being unpatentable over Kehne under *35 U.S.C. Section 102*/103. Apparently, the examiner regarded the Kehne patent as being prior art.

53. In a second rejection, claim 13 appears to have been rejected on the ground that **[*1543]** applicants are somehow attempting to recapture subject matter contrary to *35 U.S.C. Section 251.*

54. In a third rejection, Claim 13 appears to have been rejected as being unpatentable over the "lost" counts, i.e., the subject matter of Counts 1-3 (Final Rejection, Paper 17, page 4). Apparently, the examiner was of the opinion that the subject matter of claim 13 is not patentably distinct from the subject matter of the lost counts. If the examiner's opinion is correct, then claim 13 would be unpatentable under the rationale of *In re Deckler , 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992)* (junior party losing interference to senior party based on senior party's foreign priority date is not entitled to claims to same patentable invention as count--based on estoppel). See also *Ex parte Tytgat , 225 USPQ 907 (Bd. App. 1985).*

B. Discussion

1. The examiner's first rejection--prior art The examiner's first ground of rejection seems to assume that the Kehne patent is somehow prior art vis-a-vis applicants.

Applicants, however, have a priority date which is earlier than the Section 102(e) date of Kehne. Accordingly, the Kehne patent per se is not prior art. Compare *In re Hilmer , 359 F.2d 859, 149 USPQ 480 (CCPA 1966),* and *In re Hilmer , 424 F.2d 1108, 165 USPQ 255 (CCPA 1970).*

The examiner's first rejection is reversed .

2. The examiner's second rejection--recapture We do not understand the examiner's recapture rationale. Ordinarily, a rejection in a reissue application based on recapture involves a showing that during prosecution of the application which matured into the patent, the applicant gave up subject matter in the face of the prior art which is attempted to be "recaptured" through reissue. See e.g. , Hester Industries, Inc. v. Stein, Inc. , *142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998),* and *In re Clement , 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997).*

The examiner has not established that applicants are attempting to recapture subject matter surrendered during

prosecution of the application which matured into the patent here sought to be reissued.

Go to Headnotes [**1R] We would note that a rejection based on estoppel arising out of an interference and a rejection based on recapture are bottomed on different rationales. Hence, an examiner should not attempt to create a recapture rejection based on subject matter lost during an interference. Rather, the proper rejection is one based on Rule 658(c) dealing with estoppel.

3. The examiner's third rejection--estoppel a. Introduction We begin our discussion by saying that the decision of the examiner to reject based on an estoppel was correct. However, the examiner's rationale in support of his decision is not sufficient to justify his third rejection. We will affirm the examiner's decision , but we will designate our affirmance as a new ground of rejection under 37 CFR Section 1.196(b).

We wish to make clear that the sole rationale upon which our affirmance is based is that set out in this MEMORANDUM OPINION and ORDER.

b. The new ground of rejection Claim 13 will be rejected on alternative, and probably inconsistent, grounds.

Claim 13 is rejected (1) based on estoppel under Rule 658(c) for failure to take action during Interference 103,406 to place the subject matter of claim 13 in issue inter partes in an interference or (2) based on the rationale of *In re Deckler , supra* .

If, as applicants maintain, claim 13 defines an invention which is separately patentable from the subject matter of lost Counts 1-3, then applicants are not entitled to claim 13 based on applicants failure to have moved to add the reissue application and a new count to Interference 103,406. Rule 658(c); Rule 633(c)(1); *In re Rhodes , 23 CCPA 816, 80 F.2d 525, 28 USPQ 75 (1936),* the vitality of which was reaffirmed in *Steinmayer v. Ramsey , 30 CCPA 802, 132 F.2d 1007, 56 USPQ 374 (1942).* Alternatively, applicants are estopped under Rule 658(c) for failure to move under 37 CFR Section 1.633(e) to have a second interference declared between applicants and Kehne involving the allegedly separately patentable subject matter of applicants' claim 13.

If, as the examiner maintains, claim 13 defines an invention which is not separately patentable from the subject matter of lost Counts 1-3, then claim 13 is not patentable based on the proposition that a party losing an interference is not entitled to claim an invention which is not separately patentable from the lost count. *In re Deckler , supra* .

There is no apparent reason to resolve the issue of whether claim 13 defines an [*1544] invention which is separately patentable from lost Counts 1-3. Applicants are not entitled to claim 13 regardless of how the issue is resolved. In this respect, we call attention to *In re Krauch , 19 CCPA 1003, 56 F.2d 290 [ 12 USPQ 257* ] (1932). In Krauch , the Commissioner urged, and the CCPA agreed, that Krauch's claims were unpatentable on alternative theories that (1) the Krauch's claims did not read on his application, n8 but (2) if they had, they would have been unpatentable for failure to move to place the subject matter in issue in a prior interference lost by Krauch. The CCPA notes, *19 CCPA at 1003, 56 F.2d at 291:*

> n8 Today we would say that the subject matter of Krauch's claims is unpatentable for failure to comply with the description requirement of the first paragraph of *35 U.S.C. Section 112.*

It seems unnecessary for us to consider the question of consistency or lack of consistency in the positions taken by the tribunals or appellants in this case * * *, because, as been aptly suggested by the solicitor for the Patent Office in his

brief * **, since it makes no difference whether the appealed claims read upon the disclosure or do not read upon the disclosure, the result is the same.

Accordingly, it becomes unnecessary for us to evaluate the Sakashita declarations on the merits. Rather, we proceed to (1) a discussion of why applicants are not entitled to claim 13 and (2) an analysis of the arguments made by applicants in their Appeal Brief.

c. Brief history of estoppel based on failure to move In 1907, the Court of Appeals for the District of Columbia (now the U.S. Court of Appeals for the District of Columbia Circuit), determined that the principles of res judicata apply to interferences. *Blackford v. Wilder , 28 App. D.C. 535, 1907 Dec. Comm'r Pat. 491 (1907).* Specifically, the court noted in an appeal of a second interference between Blackford and Wilder, that *(28 App. D.C. at 550, 1907 Dec. Comm'r Pat. at 501* (emphasis added)):

To sum up--the parties are the same. The applications are the same and disclose the invention of each issue.[ n9 ] The constructions relied on, respectively, as evidencing conception and reduction to practice of the invention of both issues are the same. The fundamental facts of both cases are the same. Applying the well-settled principle of estoppel by judgment, before stated,[ n10 ] it follows inevitably that the final decision in the first interference is conclusive, unless it can be made to appear that the question upon which the determination of the second case rests is one that neither was, nor could have been presented and determined in the first case .

n9 During the earlier part of the 20th Century, the Patent Office and courts often referred to the "issue" in an interference. The term "issue" then meant what "count" means today. Thus, "issue" and "count" mean the same thing.

n10 The court refers to the doctrine of res judicata , or estoppel by judgment, as enunciated by the Supreme Court in *Nesbit v. Riverside Independent District , 144 U.S. 610, 618 (1892); New Orleans v. Citizens Bank , 167 U.S. 371, 386 (1897);* and *S.P.R. v. United States , 168 U.S. 1, 48 (1897).* See *28 App. D.C. at 542, 1907 Dec. Comm'r Pat. at 496.*

(1) Rule 109 There came a time when the Patent Office promulgated a regulation which was identified as Rule 109. The regulation set out the kinds of motions (now referred to as preliminary motions) which a party might file during an interference. The early CCPA cases dealing with estoppel based on a lost interference refer to Rule 109. At the time of *In re Rhodes , supra ,* Rule 109 provided as follows: n11

n11 Reproduced from Rules of Practice in the United States Patent Office , pages 33-34 (Revised 1 October 1927), as published by the United States Government Printing Office.

An applicant involved in an interference may * * *, on motion duly made * * *, file an amendment to his application containing any claims which in his opinion should be made the basis of interference between himself and any of the other parties. Such motion must be accompanied by the proposed amendment * * *. On the admission of such amendment and adoption of the claims by the other parties * * *, the primary examiner shall redeclare the interference or shall declare such other interferences as may be necessary to include the said new claims.

Any party to an interference may bring a motion to put in interference any claims already in his application or patent which in his opinion should be made the basis of interference between himself and any of the other parties. Any party to an interference may bring a motion to substitute any other application owned by him, as to the [*1545] existing issue, or to include an application or a patent owned by him, as to claims which he deems should be made the basis of interference between himself and any of the other parties * * *.

A number of early CCPA decisions dealt with the issue of estoppel based on a failure of a losing party to move to place subject matter in issue during an interference and then attempting to claim the subject matter post-interference or in a second interference. See , e.g. the following non-exhaustive list of early CCPA cases:

(1) *In re Austin , 17 CCPA 1202, 40 F.2d 756 [ 5 USPQ 285 ]* (1930) (losing party estopped); (2) *In re Chase , 21 CCPA 1183, 71 F.2d 178 [ 22 USPQ 77 ]* (1934) (losing party not estopped), but overruled in *Avery v. Chase , 26 CCPA 823, 101 F.2d 205, 40 USPQ 343 (1939),* an appeal involving a second interference between Avery and Chase; (3) *In re Rhodes , 23 CCPA 816, 80 F.2d 525 [ 28 USPQ 75 ]* (1936) (losing party estopped), which as noted earlier, was reaffirmed in *Steinmayer v. Ramsey , 30 CCPA 802, 132 F.2d 1007, 56 USPQ 374 (1942);* (4) *In re Long , 23 CCPA 1078, 83 F.2d 458 [ 29 USPQ 357 ]* (1936) (losing party no estopped); (5) *Anderson v. Shaw , 24 CCPA 951, 87 F.2d 903 [ 32 USPQ 512 ]* (1937) (in a second interference, a party who lost a first interference was held to be estopped based on a failure to move under Rule 109 in the first interference). n12 (6) *In re Sawyer , 36 CCPA 1054, 173 F.2d 1004, 81 USPQ 374 (1949)* (reissue applicant estopped to claim subject matter following loss in interference where subject matter was described in opponent's specification and reissue applicant failed to move under Rule 109 to place subject matter in issue); and (7) *In re Bronstein , 38 CCPA 887, 187 F.2d 637, 89 USPQ 66 (1951)* (losing party estopped).

n12 A decision in an ex parte case that an applicant is not estopped is not binding in a second interference on the party who won the first interference. Under today's rules, a party in a second interference, who believes its opponent is estopped based on what occurred or did not occur in a first interference, may file a preliminary motion for judgment based on estoppel. 37 CFR Section 1.633(a).

(2) Rule 231 Through passage of time and a series of rule revisions, Rule 109 became Rule 231. See , e.g. , *Meitzner v. Mindick , 549 F.2d 775, 781, n.6, 193 USPQ 17, 22 n.6* (CCPA), cert. denied , *434 U.S. 854 (1977)* (holding that Meitzner was estopped in a third interference from claiming subject matter based on its having failed to contest priority on that subject matter in a first, and possibly a second, interference).

Rule 231 [37 CFR Section 1.231 (1984)] provided, in relevant part:

(a) [A]ny party to an interference may file a motion seeking:

* * * * * (2) To amend the issue by addition * * * of new counts. Each such motion must contain an explanation as to why a count proposed to be added is necessary * * *.

(3) To * * * declare an additional interference to include any other application owned by him as to any subject matter other than the existing issue but disclosed in his application or patent involved in the interference and in the opposing party's application or patent in the interference which should be made the basis of interference with such other party.

* * * * *.

(3) 37 CFR Section 1.658 [Rule 658(c)] The interference rules were revised in 1984. As part of the rule revision, the Commissioner promulgated 37 CFR Section 1.633 authorizing parties to file preliminary motions and 37 CFR Section 1.658(c) [Rule 658(c)] defining estoppel. Rule 658(c) provides:

[a] judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a [preliminary] motion under Section 1.633 (a) through (d) and (f) through (j) or [a motion] Section 1.634 and (3) could have been properly raised and decided in an additional interference with a [preliminary] motion under Section 1.633(c). A losing party who could have properly moved, but failed to move, under Sections 1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is **[*1546]** inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment.

Rule 633 [37 CFR Section 1.633], previously discussed, permits a party to file a preliminary motion to add a reissue and a preliminary motion to add a count. Rule 633 also permits a party to seek an additional interference between an application owned by the party and an application or patent owned by an opponent where both parties describe an invention which is separately patentable from the count of the interference in which the preliminary motion is to be filed.

In the Notice of Final Rule, Patent Interference Practice, *49 Fed. Reg. 48416* (Dec. 12, 1984), reprinted in *1050 Off. Gaz. Pat. Office 385* (Jan. 29, 1985), the Commissioner makes the following observation, setting out examples of how estoppel under Rule 658(c) would be implemented (49 Fed. Reg. beginning at 48426, col. 2) (Example 27 is essentially the facts in this appeal):

Section 1.658(c) creates an estoppel both as to senior and junior parties unlike the present practice (37 CFR 1.257) which limits estoppel in some instances to junior parties. An estoppel would not apply with respect to any claims which correspond, or which properly could have corresponded, to a count as to which the party was awarded a favorable judgment. A few examples illustrate how estoppel would be applied. Example 24 . Junior party applicant AL and senior party applicant AK both disclose separate patentable inventions "A" and "B" and claim only invention A in their respective applications. An interference is declared with a single count to invention A. Neither party files a preliminary motion (see Section 1.633(c)(1)) to add a count to invention B. Judgment as to all of AL's claims corresponding to the sole count is awarded to junior party applicant AL. Senior party applicant AK would be estopped to thereafter obtain a patent containing claims to invention B, because applicant AK failed to move to add a count to invention B in the interference. Junior party applicant AL would not be estopped to obtain a patent containing claims to invention B. Example 25 . In this example, the facts are the same as in Example 24 except that judgment is awarded as to all AK's claims corresponding to the count to senior party applicant AK. Junior party applicant AL would be estopped to obtain a patent containing claims to invention B in the interference. Senior party applicant AK would not be estopped to obtain a patent containing claims to invention B. Example 26 . Junior party applicant AM and senior party applicant AP both disclose separate patentable inventions "C", "D", and "E" and claim inventions C and D in their respective applications. An interference is declared with two counts. Count 1 is to invention C and Count 2 is to invention D. Neither party files a preliminary motion to add a proposed Count 3 to invention E. Judgment as to all AM's claims corresponding to Counts 1 and 2 is awarded to junior party applicant AM. Senior party applicant AP would be estopped to thereafter obtain a patent containing claims to invention E, because applicant AP failed to move to add a count to invention E in the interference. Junior party applicant AM would not be estopped to obtain a patent containing claim to invention E. Example 27 . In this example, the facts are the same as in Example 26 except that judgment is awarded as to all AP's claims corresponding to Counts 1 and 2 to senior party applicant AP. Junior party applicant AM would be estopped to obtain a patent containing claims to invention E, because applicant AM failed to move to add a count to invention E in the interference. Senior party applicant AP would not be estopped to obtain a patent containing claims to invention E.

The Commissioner further observed *(49 Fed. Reg. at 48441,* col. 2):

[p]arties in interference cases should recognize, * * * that the interference estoppel provisions of Section 1.658(c) have been expanded with the view to eliminating much of the ex parte maneuvering which has taken place in the past after an interference is terminated. Accordingly, a party who fails to move to place a matter in issue runs a considerable risk that the party will not be able to raise the issue ex parte after an interference is terminated.

With respect to the failure of a losing party to file a preliminary motion under 37 CFR Section 1.633(e) to have an additional interference declared, the Commissioner made the following observation *(49 Fed. Reg. at 48440,* col. 2):

One comment pointed out that Section 1.633(e) adopts the estoppel rule approved by the Court of Customs and Patent Appeals in *Avery v. Chase , 101 F.2d 205, 40 USPQ 343 (CCPA 1939),* cert. denied , *307 U.S. 638 (1939),* while rejecting the rule [**1547] announced by the U.S. Court of Appeals for the District of Columbia Circuit in *International Cellucotton Products Co. v. Coe , 35 F.2d 869, 30 USPQ 366 (D.C. Cir. 1936).* See also *American Cyanamid Co. v. Coe , 106 F.2d 851, 42 USPQ 302 (D.C. Cir. 1939).* The commentator is correct in noting that the rules adopt the estoppel rule approved in Avery v. Chase . The following comment by the CCPA in its opinion in *In re Shimer , 69 F.2d 556, 558, 21 USPQ 161, 163 (CCPA 1934),* accurately expresses the intent of the PTO in promulgating Sections 1.633(e) and 1.658(c):

It may be stated that this rule works no hardship to him who is diligent in pursuit of his rights. When an interference is declared, the files of his contestants are open to him. He has full cognizance of their disclosures and claims. So advised, it becomes his duty to put forward every claim he has. [Rule 1.633(e)] . . . affords him this opportunity. If the rule be not enforced or enforceable, then delays and litigation are greatly increased. It is quite obvious that the doctrine of estoppel, as applied in these cases, results in the better conduct of the business of the Patent [and Trademark] Office and in the public good.

There have been few, if any, reported cases involving estoppel under Rule 658(c) based on (1) a failure to move to add a count and/or (2) a failure to move to have a second interference declared. Accordingly, we take this opportunity to discuss practice under Rule 658(c).

As noted in *In re Shimer , supra , 69 F.2d at 558, 21 USPQ at 163* , estoppel benefits three separate entities, (1) the winning party, (2) the Patent and Trademark Office and (3) the public. Rule 658(c) serves all three interests.

First, Rule 658(c) benefits the winning party in an interference. The winning party knows that its losing opponent will not be able to claim subject matter which the losing opponent could have placed in issue in the interference.

Secondly, Rule 658(c) benefits the efficient administration of justice in patent cases before the Patent and Trademark Office. Having been willing to consider the issue in an interference when the PTO would have had the benefit of the opposing views of adverse parties, Rule 658(c) provides a vehicle for precluding a losing party applicant from continuing in effect to prosecute the interference ex parte when the applicant could have done so inter partes in the interference.

Third, Rule 658(c) benefits the public, giving the public assurance that an interference resolved all issues which might have been raised. The public is afforded the desirable comfort of knowing that it can negotiate with and license from the winning party reasonably confident that the losing party will not somehow obtain a second patent to the same patentable invention or a separate patentable invention which could have been placed in issue in the interference.

d. Estoppel based on the prior judgment If, as the examiner maintains, the subject matter of claim 13 is directed to the same patentable invention as the subject matter of lost counts 1-3, then applicants are not entitled to claim 13. *In re Deckler , supra* . Deckler notes, *977 F.2d at 1452, 24 USPQ2d at 1449* :

The interference judgment conclusively determined that, as between Deckler and Grataloup, Grataloup was entitled to claim the patentable subject matter defined in the interference count. It is therefore proper, and consistent with the policies of finality and repose embodied in the doctrines of res judicata and collateral estopped, to use that judgment as a basis for rejection of claims to the same patentable invention.

Also relevant is *In re Kroekel , 803 F.2d 705, 231 USPQ 640 (Fed. Cir. 1986).* Kroekel lost an interference to Comstock. After resumption of ex parte prosecution in the Kroekel application, Kroekel attempted, in claim 40, to claim subject matter described by Kroekel.

The Federal Circuit held that Kroekel was estopped to claim the subject matter of claim 40, because it had not been shown to be patentably distinct from the interference count. n13

> n13 The Federal Circuit also noted that had Kroekel (1) attempted to broaden the interference count to include the subject matter of his claim 40 and (2) been precluded from doing so, Kroekel would not have been estopped. *803 F.2d at 710, 231 USPQ at 643* .

e. Estoppel based on failure to move Go to Headnotes **[**2R]** If, as applicants maintain, the subject matter of claim 13 is not the same patentable invention as lost Counts 1-3, then applicants are not entitled to claim 13 based on their [*1548] failure to move to put the subject matter of claim 13 in issue in the interference or an additional interference.

We have found that the subject matter of claim 13 is described by Kehne.

We also have found that applicants failed to move to (1) add their reissue and a count to the subject matter of claim 13 or (2) seek an additional interference involving their reissue application and the then Kehne application with a count to the subject matter of claim 13.

These two findings support a holding that applicants are not entitled to pursue claim 13 post-interference. In other words, the estoppel provisions of Rule 658(c) preclude applicants from now seeking a patent to claim 13. Applicants' right to a patent containing claim 13 could have been properly raised and decided in Interference 103,406 or an additional interference. Since applicants could have moved, but failed to move, to place the subject matter of claim 13 in issue inter partes , they are now estopped pursuant to Rule 658(c) from seeking that subject matter in the reissue application on appeal. Compare *In re Rhodes , supra* .

f. Discussion of applicants' arguments We have considered the arguments made in applicants' briefs before us.

(1) Applicants' contention that it could not have moved Applicants maintain that they could not have moved to put the subject matter of claim 13 in issue in the interference. Their argument would appear to be bottomed on the following rationale. Claim 13 defines an invention which is separately patentable from lost Counts 1-3. There is no provision in the interference rules which permits a party to add a claim to an interference and have the claim designated as not corresponding to a count. Hence, applicants could not have moved to add claim 13 to the interference.

Applicants are correct that a party in an interference cannot file a preliminary motion to add a claim and have the claim designated as not corresponding to the count. *Winters v. Fujita , 53 USPQ2d 1234, 1248* , col. 1 (Bd. Pat. App. & Int. 1999), reconsideration denied , *53 USPQ2d 1478* (Bd. Pat. App. & Int. 2000). In addition to the discussion in Winters , we would note that the board has jurisdiction under *35 U.S.C. Section 135*(a) to resolve priority and to enter a judgment

as to claims "involved" in the interference. Arguably, it might be inconsistent with law to permit a preliminary motion to add a claim which was not going to be "involved" in the interference.

Applicants' argument completely overlooks the fact that both applicants and Kehne describe the invention of claim 13. Accordingly, no preliminary motion would have been necessary to designate claim 13 as not corresponding to lost Counts 1-3. The proper preliminary motion would have been one which placed the subject matter of claim 13 in issue between applicants and Kehne. It thus becomes apparent that applicants' "straw-man" argument is a side-show apart from the main event.

(2) The separate patentability of claim 13 vis-a-vis lost Counts 1-3 Applicants maintain that the subject matter of claim 13 is separately patentable from the subject matter of lost Counts 1-3. For reasons already given, we find it unnecessary to resolve the separate patentability issue. Compare *In re Krauch , 19 CCPA 1003, 56 F.2d 290 [ 12 USPQ 257* ] (1932).

(3) The settlement agreement and Kehne's alleged position Go to Headnotes **[**3R]** Applicants make the argument that Kehne's assignee "will not claim * * * [the invention] of claim 13." Appeal Brief, page 9. The argument is essentially irrelevant. The mere fact that Kehne did not claim the subject matter of claim 13 in no way is a statement that Kehne believes applicants are entitled to claim 13. Moreover, the argument is essentially irrelevant because Rule 658(c) operates independently from the views of the winning party. As noted in *Shimer , supra ,* estoppel for failure to move also benefits the PTO and the public.

In an argument we find most unusual, applicants note that the "Board accepted this settlement agreement." Appeal Brief, page 9. The inference, we suppose, is that when the PTO "accepted" (whatever "accepted" means) the settlement agreement, the PTO also "accepted" any terms therein. Wrong!

Section 135(c) provides that agreements settling an interference must be filed. If a party timely requests that an agreement be filed, it is filed. Likewise, Section 135(c) provides that the parties may request that the agreement be maintained separate from the interference file. If a request is made to maintain the agreement separate from the file, it is always granted. Ordinarily, the board does **[*1549]** not review the content of settlement agreements. Thus, the acts of receiving timely filed settlement agreements and storing those agreements in an appropriate file (either separate from the interference file or in an interference file) are ministerial acts. Compare *Nelson v. Bowler , 212 USPQ 760* (Comm'r Pat. 1981). The board neither enforces or reviews the appropriateness of terms in settlement agreements.

(4) Applicants' proposed conclusions of law Applicants appended to their Appeal Brief proposed findings of fact and conclusions of law.

According to proposed conclusion of law 1, if a claim at issue is patentably distinct from a lost count, the claim cannot be denie to the applicants on the sole ground of interference estoppel. *In re Kroekel , supra ,* is cited in support of the proposed conclusion of law.

The following sentence appears in the Federal Circuit's opinion in *Kroekel , 803 F.2d at 710, 231 USPQ at 643* : "If claim 40 were patentably distinct from the lost count, it could not be denied to Krockel on the sole ground of interference estoppel." Based on the Federal Circuit's sentence, applicants appear to maintain that there is no "interference estoppel" in this case. But, the sentence is dicta given that the Federal Circuit held that claim 40 was directed to the same patentable invention as the lost Kroekel v. Comstock count. Moreover, there is absolutely no indication in the Kroekel opinion that the Federal Circuit intended to overrule its prior binding precedent bottomed on a failure on the part of a losing party in an interference to move to add a second count or a failure on the part of a losing party to move to declare an additional interference. Rather, it determined that " [e]stoppel should be decided on the facts of each case with reference to principles of equity." *803 F.2d at 709, 231 USPQ at 643* . As has been shown above, the equities are plainly against applicants who failed to take appropriate steps in the interference to resolve the issue of who

was first with respect to the subject matter of claim 13 and/or whether claim 13 was patentable to applicants.

In proposed conclusion of law 2, applicants state that domination by a lost count of an interference does not preclude a losing party applicant from showing a patentable distinction of a species, citing *In re Taub , 348 F.2d 556, 146 USPQ 384 (CCPA 1965).* We agree. But, Taub did not involve a refusal based on Taub's failure to move to put his 9a-fluoro species in issue. In fact, it appears that a motion by Taub to declare another interference directed to the 9a-fluoro species was filed, but denied. *Taub , 348 F.2d at 559, 146 USPQ 386* . Thus, Taub unlike applicants preserved his right to seek a patent on his 9a-fluoro species notwithstanding the fact the winning party also described that species.

C. Order

Upon consideration of the record, and solely for the reasons given, it is

ORDERED that the examiner's first rejection is reversed .

FURTHER ORDERED that the examiner's second rejection is reversed .

FURTHER ORDERED that the examiner's third rejection is affirmed .

FURTHER ORDERED that the affirmance of the examiner's third rejection is designated as a new ground of rejection under 37 CFR Section 1.196(b).

D. Applicants request for oral argument

Applicants have requested oral argument. Given our disposition of the appeal on the basis of rationale considerably different from that relied upon by the examiner in the examiner's third rejection, we believe oral argument at this time not be particularly useful.

Applicants have two options for further prosecution of our new ground of rejection. In the event applicants elect the option of filing a request for rehearing, applicants are also authorized to ask for oral argument in connection with the request for rehearing and a date for oral argument will be set.

E. Time for taking action

This MEMORANDUM OPINION and ORDER contains a new ground of rejection pursuant to Rule 196(b) (37 CFR Section 1.196(b).

Rule 196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

Rule 196(b) also provides that the applicant, WITHIN TWO MONTHS FROM THE DATE OF ENTRY OF THIS MEMORANDUM OPINION and ORDER, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (Section 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under Section 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . . **[*1550]**

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR Section 1.136(a).

AFFIRMED (37 CFR Section 1.196(b))

LEXSEE 17 USPQ2D 1716

Ex parte

Appeal No. 89-2432 from Art Unit 122.

Application for Patent filed February 28, 1986, Serial No. 834,577.

Quinolonecarboxylic Acid Derivative and Process for Its Preparation.

Board of Patent Appeals and Interferences

*1990 Pat. App. LEXIS 19; 17 U.S.P.Q.2D (BNA) 1716*

May 22, 1990, Heard
June 5, 1990, Decided

[*1]

Before Goldstein, Metz and Wiseman, Examiners-in-Chief.

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Supervisory Primary Examiner - Donald G. Daus.

Examiner - E. Bernhardt.

**OPINIONBY:** GOLDSTEIN

**OPINION:**

Goldstein, Examiner-in-Chief.

This appeal was originally taken from the examiner's final rejection of claims 1, 3 and 4. Subsequently claim 4 was cancelled. Although, at the beginning of appellants' appeal brief, it is stated that this appeal is "from the final rejection of all claims pending in this application," claim 3 was not reproduced in the brief on appeal. The examiner assumed that this omission was inadvertent but, by implication from the fact that claim 3 has not been argued separately in the brief, and from statements made upon oral hearing of this appeal, it appears likely that the rejection of claim 3 was not intended to be appealed. Nonetheless, in the event that we are mistaken in drawing this inference, we shall treat claim 3 as being on appeal. Because, as we have already indicated, no separate arguments have been presented, claim 3 may be considered to stand or [*2] fall with claim 1. *In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979).* Even so, for the sake of completeness, we shall address specific

remarks to the patentability of claim 3 in this decision.

References relied on by the examiner on appeal are:

| | | |
|---|---|---|
| Culbertson et al. (Culbertson) | 4,638,067 | Jan. 20, 1987 |
| Petersen et al. (Petersen) | 167,763 | Jan. 15, 1986 |
| Irikura (Great Britain) | 2,057,440 | Apr. 1, 1981 |

Claims 1 and 3 have been finally rejected under *35 USC 102*(a) as being anticipated by Peterson. We shall affirm this rejection.

All page references in the following discussion shall be to the English language translation of record (apparently supplied by appellants) of the European patent specification, which was originally published in German.

The examiner has adequately explained the basis of the conclusion that the reference anticipates the appealed claims and sufficiently convincingly rebutted all of appellants' arguments that we could simply adopt the examiner's position as our own, adding no further comment. However, since appellants have expressly invited us to decide what they consider to be "a significant **[*3]** policy question," n1 we feel constrained to present additional comments, both to emphasize those aspects of the examiner's position with which we agree and for the sake of completeness.

n1 The "policy question" appears to be whether or not the Patent and Trademark Office shall continue to interpret *35 USC 102*(a) literally.

Appellants have acknowledged (at least implicitly on the written record and expressly upon oral hearing) that the synthetic procedures disclosed in the reference enable the preparation of the compound * * *, which is explicitly disclosed at page 13 of the reference. It has not been controverted that the name of the compound disclosed corresponds to the formula presented in appellants' claim 1. Thus, even if there were no disclosure of utility in the reference, the examiner would have been correct in holding that the claim was anticipated, and the examiner's citation of *In re Hafner, 56 CCPA 1424, 410 F.2d 1403, 161 USPQ 783 (1969)* would have been quite appropriate. Since the reference does disclose a specific utility for the compound (generally the same utility as in the present case), this issue does not arise (but see the discussion of Claim 3, below). **[*4]**

We find only twenty-two compounds in the list presented at pages 12 to 14, disclosed in addition to those listed in the working examples, and not twenty-three as found by the examiner. There are twenty-four compounds disclosed in the working examples. In either event, forty-six or forty-seven compounds hardly amounts to the "list of thousands" referred to in *In re Wiggins, 488 F.2d 538, 543, 179 USPQ 421, 425 (CCPA 1973),* relied on by appellants. Furthermore, as the examiner has correctly pointed out, the critical issue in Wiggins was whether or not the name of a compound was a description of that compound in the absence of a known synthetic method of producing that compound. That issue does not arise on the present facts.

Even if the number of compounds disclosed in the reference were several orders of magnitude greater, we would come to the same conclusion. The tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is "described," as that term is used in *35 USC 102*(a), in that publication. A similar conclusion would be appropriate with respect to the approximately 1.5 million compounds disclosed in the **[*5]** Beilstein Handbook (Handbuch der Organischen Chemie). As a general principle it has long been held, even where the issue was one of obviousness and not clear anticipation or description, that the comprehensiveness of a reference disclosure does not derogate from its teaching effect. *Merck Co. v. Biocraft Laboratories, Inc., F.2d , 10 USPQ2d*

*1843 (Fed. Cir. 1989); In re Corkill, 771 F.2d 1496, 226 USPQ 105 (Fed. Cir. 1985). In re Susi, 58 CCPA 1074, 440 F.2d 442, 169 USPQ 423 (1971); In re Lemin, 51 CCPA 1404, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960).*

With regard to the numerous other precedents discussed by appellants, they invariably deal with a significantly different set of facts. In each case, to arrive at the claimed subject matter, it was necessary to select portions of that subject matter from various sections of the reference disclosure and combine them n2, e.g., selecting values for variable substituents to interpolate into a generic structural formula to arrive at a specific compound. Even in those cases, if the classes were sufficiently limited or well delineated, anticipation was found. **[*6]** Compare *In re Arkley, 455 F.2d 586, 172 USPQ 524 (CCPA 1972),* with *In re Sivaramakrishnan, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982), In re Schaumann, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); In re Petering, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).*

n2 Somewhat reminiscent of the lexicographer who described his dictionary as "a poem about everything," but clearly not the case here.

Of course, it goes without saying (but, equally of course, we are going to say it) that the evidence of asserted unobvious results of record is not relevant to this rejection. *In re Malagari, 499 F.2d 1297, 182 USPQ 549 (CCPA 1974).*

Claim 3, which recites "an antibacterial pharmaceutical composition" broadly, may or may not be intended to be on appeal, as we have discussed above, and no separate arguments have been drawn to this claim. Nonetheless, we shall indicate our reasons for considering the above comments to apply to essentially the same degree to the rejection of claim 3, for the sake of completeness of this record, in the event, for example, that further appeal should be taken from this decision.

As we have stated above, there are only forty-six (or forty-seven) compounds described **[*7]** specifically in the reference. The compounds are disclosed as having "antibacterial activity" and being "meant for use as active compounds in medicaments" (see Item 57 on the title page). Various types of specific pharmaceutical compositions utilizing various acceptable carriers are expressly disclosed at pages 28 to 30. The nature of this disclosure is such that we are convinced that this reference should appropriately be considered to "describe," in the sense of *35 USC 102,* pharmaceutical compositions containing each of the forty-six (or forty-seven) specific, pharmaceutically active compounds disclosed. Again, compare Arkley with Sivaramakrishnan, Schaumann and Petering.

Claims 1 and 3 have been finally rejected under *35 USC 103* as being unpatentable over Culbertson in view of Irikura. We shall not affirm this rejection.

On the issue of prima facie obviousness, we would have found the examiner's conclusion to be supported by the disclosure of Culbertson alone. That disclosure is generic to the here claimed subject matter, and the species of Example 45 differs from appellants' claimed compound only in having an 8-fluoro substituent in place of an substituent. **[*8]**

With regard to this rejection under *35 USC 103,* appellants evidence of asserted unobvious results is relevant. We have considered that evidence, specifically the declaration of Irikura, under 37 CFR 1.132, and we disagree with the examiner's conclusion. It is the examiner's position that, to rebut the evidence of obviousness, it is necessary for the claimed compound to be unexpectedly different from the reference compounds "overall," i.e., in its therapeutic effect against all bacteria. However, appellants' thesis is that their compound is unexpectedly and significantly superior against anaerobic bacteria, a property which makes it unexpectedly suited for a specific, important utility. Conceptually, this can be the basis for overcoming a prima facie case of obviousness. *In re Chupp, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1986); In re Murch, 464 F.2d 1051, 175 USPQ 89 (CCPA 1972).* The issue in each case is the weight of the actual evidence of unobviousness presented, balanced against the weight of obviousness of record.

In the declaration (page 2, first complete paragraph), it is indicated that a difference in minimim inhibitory concentration of a factor of two is [*9] considered to be "activity . . . on the same level." Even when this consideration is taken into account, however, appellants' claimed compound is significantly more active n3 against the first seven species of anaerobic bacteria listed in Table 1-b. Furthermore, Figures 1a and 1b illustrate that appellant's compound, when administered in the same dosage, provides substantially higher serum levels, for at least two hours at low doses and a substantially longer period of time at higher doses. In the absence of any explanation to support a holding to the contrary, we accept the conclusion at page 11 of the declaration that the evidence indicates "superiority" and that the "superiority was unexpected." In view of the precedents cited above, we find this evidence of unexpected superiority adequate to outweigh the evidence of obviousness found in the references adduced by the examiner.

n3 When compared to the compound of Culbertson Example 45, which the examiner agrees is the closest prior art compound of record.

The decision of the examiner is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR 1.136(a). See the final [*10] rule notice, *54 F.R. 29548 (July 13, 1989), 1105 O.G. 5* (August 1, 1989).

AFFIRMED

**Legal Topics:**

For related research and practice materials, see the following legal topics:
Patent LawInequitable ConductEffect, Materiality & ScienterGeneral OverviewPatent LawNonobviousnessEvidence & ProcedurePrima Facie ObviousnessPatent LawU.S. Patent & Trademark Office ProceedingsFiling RequirementsTranslations

1 of 2 DOCUMENTS

**NET MONEYIN, INC., Plaintiff-Appellant, v. VERISIGN, INC., Defendant-Appellee, and EPROCESSING NETWORK, Defendant-Appellee, and BANKCARD CENTER, INC., WEBTRANZ, VALIDPAY.COM, INC., ORDERBUTTON.NET, INC., SECUREPAY.COM, INC., GLOBILL.COM LLC, IB HOLDING COMPANY, LTD., E-COMMERCE EXCHANGE LLC, ITRANSACT.COM INFOSPACE, INC., CITIBANK, and ELECTRONIC PAYMENT PROCESSING, INC., Defendants.**

**2007-1565**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***545 F.3d 1359*; *2008 U.S. App. LEXIS 21827*; *88 U.S.P.Q.2D (BNA) 1751***

**October 20, 2008, Decided**

**PRIOR HISTORY: [**1]**

Appeal from the United States District Court for the District of Arizona in case no. 01-CV-441, Judge Raner C. Collins.

*Net Moneyin v. VeriSign Inc., 2007 U.S. Dist. LEXIS 98227 (D. Ariz. July 13, 2007)*

**COUNSEL:** William A. Birdwell, Davis Wright Tremaine LLP, of Portland, Oregon, argued for plaintiff-appellant. With him on the brief was Timothy R. Volpert. Of counsel on the brief was Allen Field, Law Office of Allen Field, of Portland, Oregon.

J. Michael Jakes, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, argued for defendants-appellees. With him on the brief for Verisign, Inc., were Thomas W. Winland and Scott A. Herbst, of Palo Alto, California.

Corby R. Vowell, Goldstein, Faucett & Prebeg, LLP, of Houston, Texas, for defendant-appellee EProcessing Network.

**JUDGES:** Before LINN, CLEVENGER, and MOORE, Circuit Judges.

**OPINION BY:** LINN

**OPINION**

**[*1362]** LINN, *Circuit Judge*.

Net MoneyIN, Inc. ("NMI") appeals from a final judgment of the United States District Court for the District of Arizona, which held the asserted claims of *U.S. Patents No. 5,822,737 ("the '737 patent")* and *No. 5,963,917 ("the '917 patent")* invalid. NMI also appeals from the district court's denial of its motion for leave to amend its complaint to assert a claim for inducement of infringement. Because the district court correctly **[**2]** found claims 1, 13, and 14 of the *'737 patent* and claim 1 of the *'917 patent*, which contain limitations in means-plus-function format, invalid under *35 U.S.C. § 112 P 2* as lacking corresponding structure, we affirm that portion of the judgment. Because the district court did not abuse its discretion in denying NMI's motion to amend, we also affirm that ruling. Because the district court applied an incorrect standard of law in finding claim 23 of the *'737 patent* invalid as anticipated under *35 U.S.C. § 102(a)*, however, we reverse the grant of summary judgment of anticipation. Thus, we affirm-in-part, reverse-in-part, and remand for proceedings consistent with this opinion.

I. BACKGROUND

This case involves systems for processing credit card transactions over the Internet and for addressing security concerns not present in direct retail transactions. In the early days of Internet commerce, merchants recognized that one key to the [*1363] success of Internet sales would be the ability to provide customers with assurances of security in the processing of financial transactions over the Internet using credit cards, bank accounts, and other means of electronic payment. Responding to that need, the [**3] industry investigated encryption techniques and architectures to protect sensitive data. One such effort is reflected in a 1995 working document entitled "Internet Keyed Payments Protocol ("the iKP reference"), published by the Internet Engineering Task Force and IBM. That document sets forth standards on "how payments may be accomplished efficiently, reliably[,] and securely." J.A. at 1375. The iKP reference explains that its goal was "to enable Internet-based secure electronic payments while utilizing the existing financial infrastructure for payment authorization and clearance. The intent is to avoid completely, or at least minimize, changes to the existing financial infrastructure outside the Internet." *Id.* To that end, the iKP reference suggests two standard models, or protocols. [1]

> 1 As illustrated by our colloquy with counsel at oral argument, it is not clear whether the payment models disclosed in the iKP reference are mutually exclusive. Viewing the facts in the light most favorable to NMI, however, as we must do at this stage in the proceedings, the reference is properly construed to show two mutually exclusive payment models.

In the first protocol, (1) the customer selects [**4] one or more items to purchase from the merchant's website; (2) the customer sends credit card information to the merchant; (3) the merchant sends the credit card information and amount of the purchase to the merchant's bank; (4) the merchant's bank seeks authorization for the purchase from the issuing bank over the existing banking network; and (5) the merchant's bank notifies the merchant (but not the customer) of transaction approval. *See id.* at 1381 (flow diagram); Appellant's Br. at 7.

In the second protocol, (1) the customer selects one or more items to purchase on the merchant's website; (2) the customer sends an authorization request, along with its credit card information and the amount of the purchase, to the merchant's bank; (3) the merchant's bank seeks authorization from the issuing bank over the existing banking network; (4) the merchant's bank notifies the customer of transaction approval; and (5) the customer sends the authorization response to the merchant. *See* J.A. at 1342, 1394; Appellant's Br. at 8-9.

Unsatisfied with the early approaches taken by others, Mark Ogram, an inventor and patent attorney, set out to create a new payment model to remedy what he perceived [**5] as two deficiencies in the prior art protocols: "the fact that the customer had to send confidential information over the Internet to an unknown merchant; and the fact that credit card issuers imposed onerous financial requirements on merchants." Appellant's Br. at 10. Ogram's idea was to add a fifth entity, a "payment processing" or "financial processing" entity, to supplement the conventional model with four entities: the customer, merchant, merchant's bank, and issuing bank. According to Ogram, the new financial processing entity would: "(1) receive credit card account information and an amount to be charged from the customer when the customer placed the order; (2) seek authorization from the card issuer over the existing banking network; and (3) notify both the customer and the merchant of authorization." *Id.*

On February 5, 1996, Ogram filed a patent application directed to a payment model utilizing a financial processing entity. He formed NMI shortly thereafter to [*1364] implement the model as a business for processing credit card transactions over the Internet. Ogram's patent application resulted in the *'737* and *'917 patents*, both of which are assigned to NMI. Claim 1 of the *'737 patent* [**6] is illustrative of the invention claimed:

> 1. A financial transaction system comprising:
>
> a) a first bank computer containing financial data therein, said financial data including customer account numbers and available credit data, said first bank computer including means for generating an authorization indicia in response to queries containing a customer

account number and amount;

b) a merchant computer containing promotional data;

c) a customer computer being linked with said merchant computer and receiving said promotional data; and,

d) a financial processing computer remote from said merchant computer and having means for:

1) receiving customer account data and amount data from said customer computer,

2) querying said first bank computer with said customer account data and said amount data,

3) receiving an authorization indicia from said first bank computer,

4) communicating a self-generated transaction indicia to said customer computer, and,

5) communicating the self-generated transaction indicia to said merchant computer.

According to their abstracts, the *'737* and *'917 patents* relate to "[a]n automated payment system particularly suited for purchases over a distributed computer network such [**7] as the Internet."

In 2001, NMI filed suit for infringement of the *'737* and *'917 patents* against a number of parties alleged to compete in the Internet credit card processing field, including VeriSign, Inc. and eProcessing Network (collectively, "VeriSign"). Following a claim construction hearing, the district court construed a number of terms in dispute. *Net MoneyIN, Inc. v. VeriSign, Inc.*, No. 01-CV-441 (D. Ariz. Oct. 18, 2005) ("*Claim Construction Decision*"). As part of its construction of the claim terms, the district court invalidated claims 1, 13, and 14 of the *'737 patent* and claim 1 of the *'917 patent*, which contain limitations in means-plus-function format, as lacking corresponding structure and thus indefinite under *35 U.S.C. § 112 P 2*.

Following construction of the claims, the district court entertained two motions for summary judgment that are relevant to this appeal. First, VeriSign moved for summary judgment that it did not induce infringement of NMI's patents. In response to that motion, NMI moved for leave to amend its complaint to add a claim for inducement of infringement. The district court granted VeriSign's motion for summary judgment and denied NMI's motion for leave [**8] to amend. *Net MoneyIN, Inc. v. VeriSign, Inc.*, No. 01-CV-441 (D. Ariz. June 8, 2006) ("*Amendment Decision*"). Second, VeriSign moved for summary judgment of invalidity, arguing that the iKP reference anticipated claim 23 of the *'737 patent* under *35 U.S.C. § 102(a)*. The district court granted VeriSign's motion. *Net MoneyIN, Inc. v. VeriSign, Inc., No. 01-CV-441, 2007 U.S. Dist. LEXIS 98227 (D. Ariz. July 13, 2007)* ("*Summary Judgment Decision*"). The district court then entered final judgment in favor of VeriSign.

NMI timely appealed. We have jurisdiction under *28 U.S.C. § 1295(a)(1)*.

**[*1365]** II. DISCUSSION

A. Standard of Review

Claim construction is a question of law, *Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995)* (en banc), *aff'd, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)*, over which we exercise plenary review. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998)* (en banc). Indefiniteness under *35 U.S.C. § 112 P 2* is also a question of law subject to plenary review. *SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1338 (Fed. Cir. 2005)*.

We review a grant of summary judgment de novo,

reapplying the standard that the district court employed. *Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1301 (Fed. Cir. 1999).* [**9] Drawing all reasonable inferences in favor of the nonmovant, "[s]ummary judgment is appropriate only when 'there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law.'" *Id.* (quoting *Fed. R. Civ. P. 56(c)*).

The denial of a motion to amend is a procedural question not unique to patent law and thus is reviewed under the law of the regional circuit. *Kalman v. Berlyn Corp., 914 F.2d 1473, 1480 (Fed. Cir. 1990).* In the Ninth Circuit, the denial of a motion to amend is reviewed for abuse of discretion. *Chappel v. Lab. Corp. of Am., 232 F.3d 719, 725 (9th Cir. 2000).*

B. Analysis

1. Indefiniteness

The district court concluded that claims 1, 13, and 14 of the *'737 patent* and claim 1 of the *'917 patent* were indefinite under *35 U.S.C. § 112 P 2*, and thus invalid. Because each of these patents raises different issues, we address them separately.

a. the *'737 patent*

Claim 1 of the *'737 patent* recites a financial transaction system comprising, among other things, "a first bank computer containing financial data therein, said financial data including customer account numbers and available credit data, said first bank computer including *means* [**10] *for generating an authorization indicia* in response to queries containing a customer account number and amount" (emphasis added). [2] The district court construed the generating means element in claim 1 as a means-plus-function element. The parties agreed that the function of the claimed means was "generating an authorization indicia in response to queries containing a customer account number and amount." The district court found, however, that the specification failed to disclose any corresponding structure to perform the claimed function. Accordingly, it deemed the claim invalid under *35 U.S.C. § 112 P 2*.

> 2 NMI does not make arguments with respect to claims 13 or 14, which contain language similar to that in claim 1. We view this as a concession that these claims rise or fall with claim 1.

NMI argues that the generating means element is not a means-plus-function element under *35 U.S.C. § 112 P 6* "because the claim itself discloses sufficient structure which performs the function of 'generating an authorization indicia in response to queries containing a customer account number and amount.'" Appellant's Br. at 21 (emphasis omitted). Alternatively, NMI contends that if the generating means [**11] claim element is properly construed as a means-plus-function element, then the specification recites sufficient structure to make the claim definite. VeriSign counters that the district court correctly concluded both that the claim does not recite sufficient structure to rebut the means-plus-function presumption and that the specification contains insufficient structure to perform the claimed function.

[*1366] *Section 112, paragraph 6, of title 35* provides that:

> An element of a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

A claim element that contains the word "means" and recites a function is presumed to be drafted in means-plus-function format under *35 U.S.C. § 112 P 6*. *Envirco Corp. v. Clestra Cleanroom, Inc., 209 F.3d 1360, 1364 (Fed. Cir. 2000).* The presumption is rebutted, however, "if the claim itself recites sufficient structure to perform the claimed function." *Id.*; *see also Sage Prods., Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1427-28 (Fed. Cir. 1997)* [**12] ("[W]here a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function, the claim is not in means-plus-function format.").

We first address NMI's contention that the presumption triggered by the presence of the word "means" in claim 1 is rebutted by the recitation of sufficient structure for performing entirely the recited function of "generating an authorization indicia." NMI contends that the language, "first bank computer containing financial data therein, said financial data

including customer account numbers and available credit data, said first bank computer . . . generating an authorization indicia in response to queries containing a customer account number and amount," is sufficient structure to rebut the means-plus-function presumption. NMI argues that an ordinary artisan would understand the "bank computer" "to be a commonly known structure for generating authorization indicia in response to queries containing a custom account number and amount." Appellant's Br. at 21, 22. VeriSign responds that the claim does not recite sufficient structure to rebut the presumption "because [**13] of the wide variety of types and classes of computers in existence, each being configurable in a variety of different ways using many different programming languages." Appellees' Br. at 28 (internal quotation marks and citations omitted).

We agree with VeriSign that the recitation in claim 1 of the "bank computer" is not sufficient to rebut the means-plus-function presumption. The bank computer is not linked in the claim as the "means" for generating an authorization indicia. Rather, the bank computer is recited as "including" those means. NMI's argument that the first bank computer constitutes sufficient structure would require the first bank computer to include a first bank computer, which is both redundant and illogical. Because the claimed generating means is a subset of the bank computer, there must be a recitation of structure that is a component of the bank computer to rebut the presumption. The claim contains no such recitation. As a result, the district court correctly concluded that the presumption of means-plus-function treatment had not been overcome.

Having concluded that the generating means recited in claim 1 is drafted in means-plus-function format, we turn to whether [**14] the specification includes a disclosure of structure sufficient to accomplish the recited function. NMI argues that "the specification does disclose a 'bank computer' and this Court's precedents do not require a description of the 'internal structure' of the 'bank computer.'" Appellant's Br. at 27 (emphasis omitted); *see also id.* at 31 ("Here, claim 1(a) itself states that the 'bank computer n' contains 'financial data' including 'customer account numbers and available credit data.' A person [*1367] skilled in the art would know that such a computer would be programmed to compare account data and amount data to those data structures and generate an authorization indicia if credit were available."). VeriSign counters that the district court correctly determined that the *'737 patent* specification fails to disclose the "structure corresponding to what, in the claimed first bank computer, performs the claimed generating function." Appellees' Br. at 51 (internal quotation marks omitted).

A patent applicant who employs means-plus-function language "must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, [**15] the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of *section 112*." *In re Donaldson Co., 16 F.3d 1189, 1195 (Fed. Cir. 1994)* (en banc). To avoid purely functional claiming in cases involving computer-implemented inventions, we have "consistently required that the structure disclosed in the specification be more than simply a general purpose computer or microprocessor." *Aristocrat Techs. Austl. Pty Ltd. v. Int'l Game Tech., 521 F.3d 1328, 1333 (Fed. Cir. 2008)*. "Because general purpose computers can be programmed to perform very different tasks in very different ways, simply disclosing a computer as the structure designated to perform a particular function does not limit the scope of the claim to 'the corresponding structure, material, or acts' that perform the function, as required by *section 112 paragraph 6*." *Id.* "Thus, in a means-plus-function claim 'in which the disclosed structure is a computer, or microprocessor, programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm.'" [**16] *Id.* (quoting *WMS Gaming, Inc. v. Int'l Game Tech., 184 F.3d 1339, 1349 (Fed. Cir. 1999)*). Consequently, a means-plus-function claim element for which the only disclosed structure is a general purpose computer is invalid if the specification fails to disclose an algorithm for performing the claimed function. *See id. at 1337-38*.

There is no dispute in this case that the specification fails to disclose an algorithm by which a general purpose bank computer "generat[es] an authorization indicia." [3] As a result, the district court correctly concluded that claims 1, 13, and 14 are indefinite under *35 U.S.C. § 112 P 2*. We therefore affirm that part of the judgment.

3 At oral argument, counsel for NMI conceded that "[t]here is nothing in the written description that expressly states what is going on inside that bank computer." Oral Arg. at 20:10-20:15,

*available at* http://oralarguments.cafc.uscourts.gov/mp3/2007-1565.mp3.

b. the *'917 patent*

Claim 1 of the *'917 patent* recites a financial transaction system comprising, among other things, "a financial processing computer . . . having automatic means responsive to [the] order for . . . receiving customer account data and amount data from [the] customer [**17] computer and [the] merchant computer." The parties do not dispute the district court's construction of this claim element as a means-plus-function element. The parties do dispute, however, the nature of the function. The district court construed the function as "the financial processing computer receives both the customer account data and amount data from both the customer computer and the merchant computer." *Claim Construction Decision* at 11. NMI argues that the district court's construction [*1368] of the function is erroneous. According to NMI, the ordinary meaning of the claim language requires that the function be construed more broadly: "[I]n response to an order, the financial processing computer: (1) receives customer account data from the customer computer, the merchant computer, or both; and (2) it also receives amount data from the customer computer, the merchant computer, or both." Appellant's Br. at 46-47. VeriSign counters that the district court correctly construed the function according to the ordinary meaning of the claim language.

The language of the function at issue was construed by the district court as specifying that both the amount data and the account data must come [**18] from both the customer computer and the merchant computer. That construction comports with and is fully supported by the language of the claim itself. NMI argues that the function is subject to a different construction, which would permit the amount data and the account data to come from the merchant computer, the customer computer, or both. The problem with NMI's proffered construction, however, is that it is different from, and broader in scope than, the construction it asserted in the district court. *See* J.A. at 1046 (arguing to the district court that "the meaning of this element is: 'the financial processing computer receives the customer account data from the customer computer and the amount data from the merchant computer via the customer computer'"). This is not merely a new argument in support of a previously presented construction, but instead is a new and more expansive construction, which may not properly be asserted on appeal. *See Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1347 (Fed. Cir. 2001)*. Because NMI's new construction is not proper on appeal, and because we see no basis on which to overturn the district court's construction, that construction [**19] is affirmed.

NMI concedes that under the district court's construction, no structure is disclosed in the specification to perform the claimed function. Appellant's Br. at 46. As a result, the claim is indefinite under *35 U.S.C. § 112 P 2*. *See Donaldson, 16 F.3d at 1195*. Consequently, we affirm the district court's determination that claim 1 of the *'917 patent* is invalid.

2. Anticipation

Claim 23 of the *'737 patent* recites an Internet payment system comprising five "links":

> a) a first link between a customer computer and a vending computer for communicating promotional information from said vending computer to said customer computer;
>
> b) a second link, initiated by said customer computer, between said customer computer and a payment processing computer, remote from said vending computer, for communicating credit card information and amount from said customer computer to said payment processing computer;
>
> c) a third link, initiated by said payment processing computer with a credit card server computer for communicating said credit card information and said amount from said payment processing computer to said credit card server computer, and for communicating, in response, an authorization indicia [**20] from said credit card server computer to said payment processing computer; []
>
> d) a fourth link between said payment processing computer and said customer

> computer for communicating a transactional indicia[;]
>
> [*1369] * * *
>
> [e)] a fifth link between the payment processing computer and said vending computer for communicating said transactional indicia.

The district court, after finding all five of these links in the iKP reference, albeit in two separate disclosed examples, concluded that claim 23 was anticipated under *35 U.S.C. § 102(a)* and therefore invalid. Specifically, the district court concluded:

> All of the limitations of claim 23 can be found within the iKP reference. A simple combination would produce the system described in claim 23 of the *737 patent*. That no specific example within iKP contains all five links does not preclude a finding of anticipation.

*Summary Judgment Decision 2007 U.S. Dist. LEXIS 98227, [slip op.] at 3*. NMI contends that the district court's combination of two disclosed examples in order to find all elements of the claim was erroneous. [4] VeriSign responds that the district court did not improperly rearrange the links in the iKP reference, but rather "merely relied on various express teachings from a single [**21] document that together completely disclose the five claimed links." Appellees' Br. at 61. Under VeriSign's theory, this was sufficient to establish anticipation, because all that is required is "that the four corners of a single, prior art document describe every element of the claimed invention." *Id.* at 61-62 (quoting *Xerox Corp. v. 3Com Corp., 458 F.3d 1310, 1322 (Fed. Cir. 2006)*). We disagree with VeriSign, and take this opportunity to clarify what a reference must show in order to anticipate a claimed invention.

> 4 Because it is on this ground that we decide this issue, we do not reach NMI's alternative grounds for reversing the district court's anticipation conclusion.

*Section 102(a)* provides that an issued patent is invalid if "the invention [therein] was . . . described in a printed publication . . . before the invention thereof by the applicant." *Section 102* embodies the concept of novelty--if a device or process has been previously invented (and disclosed to the public), then it is not new, and therefore the claimed invention is "anticipated" by the prior invention. As we have stated numerous times (language on which VeriSign relies), in order to demonstrate anticipation, the [**22] proponent must show "that the four corners of a single, prior art document describe every element of the claimed invention." *Xerox, 458 F.3d at 1322* (quoting *Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000)*). This statement embodies the requirement in *section 102* that the anticipating invention be "described in a printed publication," and is, of course, unimpeachable. But it does not tell the whole story. Because the hallmark of anticipation is prior invention, the prior art reference--in order to anticipate under *35 U.S.C. § 102*--must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements "arranged as in the claim." *Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 1548 (Fed. Cir. 1983)*. [5]

> 5 VeriSign points to language in *Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004)*, on which the district court relied, which states: "Apotex is of course correct that anticipation requires that all limitations of the claimed invention are described in a single reference, rather than a single example in the reference." This does not say what VeriSign wishes it did, nor could [**23] it. This language, when read in context, stands for the unremarkable proposition that courts are not constrained to proceed example-by-example when reviewing an allegedly anticipating prior art reference. Rather, the court must, while looking at the reference as a whole, conclude whether or not that reference discloses all elements of the claimed invention arranged as in the claim.

[*1370] The meaning of the expression "arranged as in the claim" is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all of the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitations of the claimed invention "arranged as in the claim." But the "arranged as in the claim" requirement is not limited to such a narrow set of "order of limitations" claims. Rather, our precedent informs that the "arranged as in the claim" requirement applies to all claims and

refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a [**24] particular order. The test is thus more accurately understood to mean "arranged or combined in the same way as in the claim."

For example, in *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452 (Fed. Cir. 1984)*, we reviewed a district court's determination that a patent directed to a hydraulic scrap shearing machine was anticipated by a prior patent directed to a method for shearing spent nuclear fuel bundles. Because the district court had "treated the claims as mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning," we reversed. *Id. at 1459*. Although the prior art reference could be said to contain all of the elements of the claimed invention, it did not anticipate under *35 U.S.C. § 102* because it "disclose[d] an entirely different device, composed of parts distinct from those of the claimed invention, and operating in a different way to process different material differently." *Id. at 1458*. The reference thus was deficient because it did not disclose the elements of the claimed invention "arranged as in the claim" as required by *35 U.S.C. §102*. *Id.*

In *Ecolochem, Inc. v. Southern California Edison Co., 227 F.3d 1361 (Fed. Cir. 2000)*, [**25] we reviewed a district court's decision that a prior art reference directed to "Saving Energy by Catalytic Reduction of Oxygen in Feedwater" anticipated a claim reciting the use of hydrazine with a mixed resin bed to deoxygenate water. In finding that the reference anticipated the claim, the district court considered a figure and accompanying text, which taught the use of hydrogen with a mixed bed to deoxygenate water, in conjunction with a separate passage discussing deoxygenating water with, among other things, hydrazine. *Id. at 1369*. We reversed. After determining that the relevant figure and accompanying text described only the use of hydrogen to deoxygenate water, we concluded that the reference could not anticipate the claimed invention because there was no link between that figure and the general discussion of hydrazine as a deoxygenating agent. *Id.* In other words, we concluded that although the reference taught all elements of the claim, it did not contain a discussion suggesting or linking hydrazine with the mixed bed in the figure, and thus did not show the invention arranged as in the claim.

Recently, in *Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323 (Fed. Cir. 2008)*, [**26] we reversed a district court's denial of a motion for judgment as a matter of law because the jury could not have reasonably concluded that the prior art reference relating to the Videotex architecture did not anticipate the claimed invention directed to systems and methods for scheduling transmission of database tiers on demand at varying repetition rates. Although the anticipation issue dealt largely with the interpretation of the prior art reference, *id. at 1335-37*, we reemphasized [*1371] the importance of the requirement that the reference describe not only the elements of the claimed invention, but also that it describe those elements "arranged as in the claim":

> To anticipate a claim, a single prior art reference must expressly or inherently disclose each claim limitation. . . . But disclosure of each element is not quite enough--this court has long held that "[a]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention *arranged as in the claim*."

*Id. at 1334* (quoting *Connell, 722 F.2d at 1548*). In all of these cases, the prior art reference had to show the claimed invention arranged or combined in the same way as recited in the claim in order [**27] to anticipate. We thus hold that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under *35 U.S.C. § 102*.

Here, the iKP reference discloses two separate protocols for processing an Internet credit card transaction. Neither of these protocols contains all five links arranged or combined in the same way as claimed in the *'737 patent*. Thus, although the iKP reference might anticipate a claim directed to either of the two protocols disclosed, it cannot anticipate the system of claim 23. The district court was wrong to conclude otherwise.

The district court was also wrong to combine parts of the separate protocols shown in the iKP reference in

concluding that claim 23 was anticipated. Granted, there may be only slight differences between the protocols disclosed in the iKP reference and the system of claim 23. But differences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation. **[**28]** *See 35 U.S.C. § 103(a)* ("A patent may not be obtained though the invention is not *identically* disclosed or described as set forth in *section 102* of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." (emphasis added)); *see also In re Arkley, 455 F.2d 586, 587, 59 C.C.P.A. 804 (CCPA 1972)* ("[R]ejections under *35 U.S.C. § 102* are proper only when the claimed subject matter is identically disclosed or described in the prior art." (emphasis and internal quotation marks omitted)). Thus, it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention. *See Arkley, 455 F.2d at 587* ("[T]he [prior art] reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without *any* need for picking, choosing, and combining **[**29]** various disclosures not directly related to each other by the teachings of the cited reference.").

Because the parties do not contend that the iKP reference discloses all of the limitations recited in claim 1 arranged or combined in the same way as in the claim, and because it was error for the district court to find anticipation by combining different parts of the separate protocols in the iKP reference simply because they were found within the four corners of the document, we reverse the district court's grant of summary judgment of invalidity.

**[*1372]** 3. Motion to Amend

During the course of this litigation, NMI filed a Second Amended Complaint in which it clarified that it was asserting, among other things, a claim for inducement of infringement under *35 U.S.C. § 271(b)*. In a Third Amended Complaint filed in August 2003, however, NMI abandoned its claim for inducement of infringement, stating that it had "elected not to assert a cause of action for inducement." In answering NMI's Third Amended Complaint, although some of the defendants reasserted counterclaims for declaratory judgment of noninfringement by inducement, VeriSign did not. J.A. at 1251.

In May 2005, VeriSign moved for partial summary **[**30]** judgment on inducement of infringement. In response, NMI moved, pursuant to *Federal Rule of Civil Procedure 15(b)*, for leave to file a Fourth Amended Complaint to add a claim for inducement of infringement. According to NMI, VeriSign had consented to litigate the issue by moving for summary judgment on that basis. The district court granted VeriSign's motion for partial summary judgment and denied NMI's motion to amend.

NMI argues that the district court abused its discretion by denying the motion to amend. According to NMI, the district court had no discretion to deny amendment under *Rule 15(b)* because VeriSign consented to litigate the issue. VeriSign argues that, while it did seek partial summary judgment on the issue of inducement, it did so on the ground of waiver, not on the merits. Thus, according to VeriSign, it was within the district court's discretion to deny amendment.

A district court generally enjoys broad discretion when assessing the propriety of a motion to amend. *See Chappel, 232 F.3d at 725*. It does not enjoy such discretion, however, and amendment is mandatory, when an issue is tried with the express or implied consent of the parties. *See Fed. R. Civ. P. 15(b)* ("When **[**31]** an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings."); *cf. Wallin v. Fuller, 476 F.2d 1204, 1210 (5th Cir. 1973)* ("Amendment is thus not merely discretionary but mandatory in such a case.").

Thus, the first issue we must address is whether VeriSign consented, either expressly or impliedly, to litigate inducement. We agree with the district court that it did not. VeriSign's motion for partial summary judgment stated, in pertinent part,

> NMI's failure to assert any claim of contributory infringement under *Section 271(c)* in its Third Amended Complaint, its express disavowal in that pleading of any claim of inducement under *Section 271(b)*, its failure to disclose any indirect infringement theories or supporting

> evidence in its Supplemental Disclosure to VeriSign, and its failure to disclose any evidence that would establish indirect infringement, including its failure to identify any alleged direct infringer or any acts by VeriSign alleged to constitute contributory infringement, compels entry of partial summary judgment in favor of VeriSign.

J.A. at 7330. This is not an attempt by VeriSign **[**32]** to litigate induced infringement on the merits. Given NMI's repeated amendment of its complaint, including its history of dropping inducement claims only to later add them, as well as VeriSign's understanding that NMI planned to resurrect the claim at trial, it is apparent that VeriSign's motion was made to foreclose NMI's ability to later raise inducement (again). Notably, this is precisely how the district court construed NMI's motion:

> Plaintiff uses the argument that by filing [a] motion for summary judgment on **[*1373]** this issue, the Defendants are consenting to its litigation. This is not the case. Defendants are merely attempting to formally discharge this theory as a claim (as has already been indicated by Plaintiffs counsel) so that the case can be focused on the theory of direct infringement.

*Amendment Decision* at 7. Thus, the district court was not without discretion to deny the requested amendment.

The question thus becomes whether the district court's denial of the motion was an abuse of that discretion. In denying the motion, the district court observed that NMI was requesting leave "to amend [its] Complaint for a fourth time in order to allege a claim (inducement of infringement) **[**33]** which [it] ha[s] expressly disavowed, twenty months after the deadline to amend pleadings and four months after the close of discovery." *Id.* at 6-7. It also observed that granting NMI's motion would result in "extreme delay," *id.* at 10, and severe prejudice to VeriSign, *id.* at 11. Under these circumstances, we cannot find that the district court's denial was an abuse of discretion. *See Chappel, 232 F.3d at 725-26* ("A district court acts within its discretion to deny leave to amend when amendment would be futile, when it would cause undue prejudice to the defendant, or when it is sought in bad faith.").

## III. CONCLUSION

For the foregoing reasons, we *AFFIRM-IN-PART*, *REVERSE-IN-PART*, and *REMAND* for proceedings consistent with this opinion.

## COSTS

No costs.

LEXSEE 533 F.3D 1353

**EISAI CO. LTD. and EISAI, INC., Plaintiffs-Appellees, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants-Appellants, and TEVA PHARMACEUTICALS USA, INC., Defendant-Appellant.**

**2007-1397, 2007-1398**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***533 F.3d 1353*; *2008 U.S. App. LEXIS 15399*; *87 U.S.P.Q.2D (BNA) 1452***

**July 21, 2008, Decided**

**SUBSEQUENT HISTORY:** Rehearing denied by *Eisai Co. v. Dr. Reddy's Labs., Ltd., 2008 U.S. App. LEXIS 25265 (Fed. Cir., Sept. 16, 2008)*
Rehearing denied by, Rehearing, en banc, denied by *Eisai Co. v. Dr. Reddy's Labs., Ltd., 2008 U.S. App. LEXIS 25264 (Fed. Cir., Sept. 16, 2008)*

**PRIOR HISTORY: [**1]**
Appeals from the United States District Court for the Southern District of New York in case No. 03-CV-9053 and 03-CV-9223, Judge Gerard E. Lynch.
*Eisai Co. v. Dr. Reddy's Labs., Ltd., 2007 U.S. Dist. LEXIS 34716 (S.D.N.Y., May 11, 2007)*
*Eisai Co. v. Teva Pharms. USA, Inc., 2006 U.S. Dist. LEXIS 73516 (S.D.N.Y., Oct. 5, 2006)*

**DISPOSITION:** AFFIRMED.

**COUNSEL:** For Joseph M. O'Malley, Jr., Paul, Hastings, Janofsky & Walker, LLP, of New York, New York, argued for plaintiffs-appellees. With him on the brief were Bruce M. Wexler, David M. Conca, Gary G. Ji, and Quinn E. Clancy.

For Maurice N. Ross, Budd Larner, P.C., of Short Hills, New Jersey, argued for defendants-appellants Dr. Reddy's Laboratories, Ltd., and Dr. Reddy's Laboratories, Inc. With him on the brief were Andrew J. Miller, Louis H. Weinstein, Ellen T. Lowenthal, and Dmitry V. Sheluho.

For Henry C. Dinger, Goodwin Procter LLP, of Boston, Massachusetts, argued for defendant-appellant Teva Pharmaceuticals USA, Inc. With him on the brief were Elaine H. Blais, and David M. Hashmall, Frederick H. Rein, and Emily L. Rapalino, of New York, New York.

**JUDGES:** Before RADER, LINN, and PROST, Circuit Judges.

**OPINION BY:** RADER

**OPINION**

**[*1355]** RADER, *Circuit Judge.*

On summary judgment, the United States District Court for the Southern District of New York found in favor of plaintiffs Eisai Co., Ltd. and Eisai, Inc. (collectively Eisai) with respect to the validity and enforceability **[**2]** of *U.S. Patent No. 5,045,552 ('552 patent)*. *Eisai Co. v. Teva Pharms. USA, Inc., No. 03 Civ. 9223, 2006 U.S. Dist. LEXIS 73516 (S.D.N.Y. Oct. 5, 2006) (SJ Validity Order); Eisai Co. v. Dr. Reddy's Labs., Ltd., 472 F. Supp. 2d 493 (S.D.N.Y. 2006) (SJ Enforceability Order)*. After a bench trial, the district court found that Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively Dr. Reddy's) and Teva Pharmaceuticals USA, Inc. (Teva) had failed to prove the remaining allegations of inequitable conduct, and that Eisai had established that Dr. Reddy's and Teva infringed Eisai's *'552 patent*. *Eisai Co. v. Dr. Reddy's*

*Labs, Ltd., No. 03 Civ. 9053, 2007 U.S. Dist. LEXIS 34716 (S.D.N.Y. May 11, 2007)* (*Trial Order*). Because the district court correctly determined that the *'552 patent* is non-obvious over the proffered prior art and that Eisai's alleged acts during prosecution did not rise to the level of inequitable conduct, this court affirms.

[*1356] I

The *'552 patent* claims rabeprazole and its salts. Rabeprazole is part of a class of drugs known as proton pump inhibitors, which suppress gastric acid production by inhibiting action of the enzyme H[+]K[+]ATPase. The distinctions between rabeprazole and its salts are not relevant for [**3] this appeal. Therefore this court refers to rabeprazole and its salts collectively as "rabeprazole." Rabeprazole's sodium salt is the active ingredient in Aciphex, a pharmaceutical approved in 1991 by the FDA for the treatment of duodenal ulcers, heartburn, and associated disorders. Aciphex has been a commercial success, garnering over $ 1 billion in worldwide yearly sales.

Dr. Reddy's and Teva each filed Abbreviated New Drug Applications (ANDAs) under the Hatch-Waxman Act, *21 U.S.C. § 355* and *35 U.S.C. § 271(e)*, seeking to manufacture a generic version of Aciphex before the expiration of the *'552 patent*. Because filing an ANDA is an artificial, but legally cognizable, act of patent infringement, *see Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1344 (2004)*, Eisai filed suit against Dr. Reddy's and Teva. Eisai also sued Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. (collectively Mylan), another ANDA filer, but that proceeding was stayed pending the outcome of these actions. Mylan agreed to be bound by the final judgments and any appeals in these cases. *Eisai Co., Ltd. v. Mylan Labs., Inc.*, No. 04 Civ. 656 (S.D.N.Y. Nov. 3, 2004). Both Dr. Reddy's and Teva conceded infringement [**4] of claims 1-6 of the *'552 patent*, but asserted that the *'552 patent* is unenforceable for inequitable conduct. *Trial Order at 6-7*. Dr. Reddy's stipulated to the validity of all six of the *'552 patent*'s claims, *id. at 6*, but Teva argued before the district court and maintains on appeal that the *'552 patent* is invalid for obviousness. Both Dr. Reddy's and Teva appeal the trial court's judgments of enforceability. Neither Dr. Reddy's nor Teva appeals the trial court's judgment of infringement. This court has jurisdiction under *28 U.S.C. § 1295(a)(1)*.

II

This court reviews a grant of summary judgment without deference. *Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362 (Fed. Cir. 2003)*. Obviousness under *35 U.S.C. § 103(a)* is ultimately a legal question, based on underlying factual determinations. *See Richardson-Vicks Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997)*. The factual determinations underpinning the legal conclusion of obviousness include 1) the scope and content of the prior art, 2) the level of ordinary skill in the art, 3) the differences between the claimed invention and the prior art, and 4) evidence of secondary factors, also known as objective indicia [**5] of non-obviousness. *Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966)*. Thus, in reviewing a district court's summary judgment of non-obviousness, this court reviews the record for genuine issues of material fact without deference, bearing in mind the movant's burden to prove invalidity by clear and convincing evidence. *See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881 (Fed. Cir. 1998)*.

Where, as here, the patent at issue claims a chemical compound, the analysis of the third *Graham* factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art [**1357] compounds. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1377 (Fed. Cir. 2006)* (noting that, for a chemical compound, a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter . . . where the prior art gives reason or motivation to make the claimed compositions" (quoting *In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990)* (en banc))). Obviousness based on structural similarity thus can be proved by identification of some motivation that [**6] would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. *See Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 (Fed. Cir. 2007)*. In keeping with the flexible nature of the obviousness inquiry, *KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 127 S. Ct. 1727, 1739, 167 L. Ed. 2d 705 (2007)*, the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. *See Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301 (Fed. Cir. 2007)*. Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close

relationship . . . to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." *Id.* (quoting *Dillon, 919 F.2d at 692*).

Teva asserts that a combination of three prior art references renders the *'552 patent* obvious: 1) European Patent No. 174,726 (owned by Takeda), claiming lansoprazole (EP '726); 2) *United States Patent No. 4,255,431* (to Junggren), claiming omeprazole (*'431 patent*); and 3) an article by Brandstrom, et al., entitled "Structure [**7] Activity Relationships of Substituted Benzimidazoles" (Brandstrom). EP '726 teaches, inter alia, the ulcer treatment compound lansoprazole. Lansoprazole differs structurally from rabeprazole at the 4-position on the pyridine ring, as indicated in the diagram below. Lansoprazole has a trifluoroethoxy (OCH[2]CF[3]) substituent, whereas rabeprazole has a methoxypropoxy (OCH[2]CH[2]CH[2]OCH[3]) substituent.

[SEE FIGURE IN ORIGINAL]

*Appellant Teva's Br.* at 28. Otherwise, the two compounds are identical. *See SJ Validity Order at 7, 2006 U.S. Dist. LEXIS 73516.* Both rabeprazole and lansoprazole are "asymmetrically substituted" with respect to the 4-position on the pyridine ring because the substituent at the 3-position (a methyl group in both compounds) is not the same as the substituent at the 5-position (a hydrogen in both compounds).

The *'431 patent* discloses a broad class of gastric acid inhibiting compounds, including omeprazole, the first commercial proton pump inhibitor, sold as Prilosec. Although sharing the same basic structure, omeprazole is structurally farther afield from rabeprazole than is lansoprazole. For instance, omeprazole's pyridine ring is symmetrically substituted and has a methoxy (OCH[3]) group at [**8] the 4-position.

Finally, Brandstrom describes a class of anti-ulcerative compounds having a benzimidazole-sulfinylmethyl-pyridine core (the Brandstrom core structure):

[*1358] [SEE [**Brandstrom Core Structure**] IN ORIGINAL]

Rabeprazole, lansoprazole, and omeprazole are all Brandstrom core structure compounds. Taking the evidence in the light most favorable to Teva, this court assumes that as per EP '726, lansoprazole is twenty times superior to omeprazole for anti-ulcer action, as measured by an indomethacin-induced gastric lesion assay in rats. This court also assumes that lansoprazole has certain traits, including lipophilicity (the ability of a compound to cross lipid membranes) and low molecular weight, that would have made it desirable to a skilled artisan.

Under these assumptions, one of skill in this art may have considered it a candidate for a lead compound in the search for anti-ulcer compounds. To the contrary, the district court emphasized the differences between anti-ulcer action and gastric acid inhibition. The trial court specifically noted that Teva's expert testified with respect to the EP '726 data that "[t]he level of acid secretion . . . from these [anti-ulcer] data . . . cannot [**9] be determined." *SJ Validity Order, 2006 U.S. Dist. LEXIS 73516, *22.* In this context, this court consults the counsel of *KSR* that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *127 S. Ct. at 1742.* Thus lansoprazole's candidacy as a starting point to develop new anti-ulcer compounds versus new gastric acid inhibitors does not resolve the lead compound analysis, at least not in the absence of any contrary indications. *Cf. Takeda, 492 F.3d at 1359* (negative side effects could dissuade one of skill from using a particular compound as a starting point).

Nonetheless, as the district court noted, the EP '726 reference teaches at best that the fluorinated substituent of lansoprazole provides "a *special path* to achieving lipophilicity." *SJ Validity Order, 2006 U.S. Dist. LEXIS 73516, *16* (emphasis in original). And Teva's expert identified a separate reference teaching that fluorine-substituted groups increase lipophilicity. *Id.* The record, however, shows no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property. [**10] Indeed, Teva's pharmacology expert, Dr. John Forte, declined to opine on lansoprazole's relevance to an examiner assessing the patentability of rabeprazole. J. A. at 14894. And Dr. Reddy's pharmacology expert, Dr. Simmy Bank, testified in deposition that "I thought [lansoprazole] had nothing to do with this trial." J. A. at 14756.

This court notes that the district court did not rigidly

limit Teva's obviousness arguments by forcing Teva to select a single lead compound. Rather Teva alone [*1359] selected lansoprazole as the anchor for its obviousness theory, not the district court. In KSR, the Supreme Court noted that an invention may have been obvious "[w]hen there [was] . . . a design need or market pressure to solve a problem and there [were] . . . a finite number of identified, predictable solutions." *127 S. Ct. at 1742* (tense changes supplied to clarify, as the Court stated and as per *35 U.S.C. § 103*, that the obviousness inquiry must rely on evidence available "at the time" of the invention, *see Takeda, 492 F.3d at 1356 n.2*). The Supreme Court's analysis in *KSR* thus relies on several assumptions about the prior art landscape. First, *KSR* assumes a starting reference point or points in [**11] the art, prior to the time of invention, from which a skilled artisan might identify a problem and pursue potential solutions. Second, *KSR* presupposes that the record up to the time of invention would give some reasons, available within the knowledge of one of skill in the art, to make particular modifications to achieve the claimed compound. *See Takeda, 492 F.3d at 1357* ("Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."). Third, the Supreme Court's analysis in *KSR* presumes that the record before the time of invention would supply some reasons for narrowing the prior art universe to a "finite number of identified, predictable solutions," *127 S. Ct. at 1742*. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008)*, this court further explained that this "easily traversed, small and finite number of alternatives . . . might support an inference of obviousness." To the extent an art is unpredictable, as the chemical arts often are, *KSR's* focus on these "identified, [**12] predictable solutions" may present a difficult hurdle because potential solutions are less likely to be genuinely predictable.

In other words, *post-KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound. Teva cannot create a genuine issue of material fact on obviousness through the unsupported assertion that compounds other than lansoprazole might have served as lead compounds. Further, the record contains no reasons a skilled artisan would have considered modification of lansoprazole by removing the lipophilicity-conferring fluorinated substituent as an identifiable, predictable solution. In sum, the district court properly concluded that the record did not support a case of obviousness of the *'552 patent* as a matter of law.

III

As with other summary judgment issues, this court reviews a district court's summary judgment on inequitable conduct without deference. *Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008)*. In contrast, where a judgment regarding inequitable conduct follows a bench trial, this court reviews the district court's findings of materiality and intent for clear [**13] error and its ultimate conclusion for an abuse of discretion. *ACCO Brands, Inc. v. ABA Locks Mfr. Co., 501 F.3d 1307, 1314 (Fed. Cir. 2007)*.

Inequitable conduct in prosecuting a patent application before the United States Patent & Trademark Office may take the form of an affirmative misrepresentation of material fact, a failure to disclose material information, or the submission [*1360] of false material information, but in every case this false or misleading material communication or failure to communicate must be coupled with an intent to deceive. *Innogenetics, 512 F.3d at 1378* (citations omitted). Materiality, defined as "what a reasonable examiner would have considered important in deciding whether to allow a patent application," and intent are both questions of fact, and require proof by clear and convincing evidence. *Id.* To satisfy the "intent" prong for unenforceability, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988)* (en banc) (citing *Norton v. Curtiss, 433 F.2d 779, 57 C.C.P.A. 1384 (CCPA 1970)*). [**14] Gross negligence is not sufficient. *Id.* This is a high bar.

On appeal, Teva and Dr. Reddy's allege that Eisai misled the Patent Office in five ways: 1) failing to disclose Eisai's own co-pending '013 application, which claimed the "ethyl homolog" of rabeprazole (compound SHKA 661); 2) withholding rejections from the '013 application's prosecution that also would have been applicable to the *'552 patent*'s prosecution; 3) failing to disclose the prior art "Byk Gulden patent" (WO 8602646); 4) submitting a misleading declaration (the Fujisaki Declaration) to the examiner of the *'552 patent*;

and 5) concealing lansoprazole from the examiner. The district court rejected the fifth assertion on summary judgment, *SJ Enforceability Order, 472 F. Supp. 2d 493, [slip op.] at 58*, and the other four after a bench trial, *Trial Order*.

Teva and Dr. Reddy's first and second allegations rely on Eisai's failure to disclose the fact of, and rejections contained in, Eisai's patent application claiming the "ethyl homolog" of rabeprazole. Known to Eisai's scientists as compound SHKA 661, the ethyl homolog differs from rabeprazole as its name suggests. SHKA 661 has one fewer methylene unit at the 4-position of the pyridine ring, giving SHKA 661 **[**15]** an ethoxy group rather than a propoxy group at this position. The district court correctly pointed out that calling SHKA 661 the "ethyl homolog" of rabeprazole in this case could carry a misleading implication with respect to inequitable conduct. The record supplies no evidence to suggest that Eisai's scientists ever referred to SHKA 661 by this name, or thought of SHKA 661 and rabeprazole "primarily in relation to each other." *Trial Order at 17 n.7*. Rather, the district court found credible the testimony that Eisai scientists considered SHKA 661 separately patentable, even though Eisai ultimately did not pursue that course. *Id. at 22-23*; *42-43*. Furthermore, even if a provisional obviousness-type double-patenting rejection might have issued in the prosecution of the '552 *patent* due to the co-pending SHKA 661 application, the district court found the materiality of this potential situation low, because applicants routinely overcome this type of rejection, *id. at 44*, by amending claims or filing a terminal disclaimer. Nonetheless, the district court did not hold that the fact of the copendency of these two applications to be totally immaterial, accurately noting that applicants should **[**16]** be encouraged to disclose closely related applications. *Id. at 47*.

While disclosure of the co-pending SHKA 661 application to the Patent Office during the prosecution of the *'552 patent* would have been prudent, Eisai's failure to do so is by no means fatal, for two reasons. First, the district court had ample evidence from which to conclude that the materiality of the SHKA 611 application **[*1361]** was low, as outlined above. Second, the record is devoid of any real suggestion of intent to deceive the Patent Office, much less the clear and convincing evidence required to support a finding of inequitable conduct.

As for the rejections of the '013 application that would have been relevant to the prosecution of the *'552 patent*, the district court did not reach materiality because it discerned insufficient proof of intent to deceive. The district court found the documentary evidence (faxed exchange between Eisai employees Mr. Shuhei Miyazawa, one of the inventors of the *'552 patent*, and Mr. Mitsuo Taniguchi, Eisai's patent agent, regarding Mr. Miyazawa's presentation to a pharmaceutical trade industry group) to supply no compelling evidence of intent, based on testimony from both parties to the fax. **[**17]** Witness credibility determinations lie squarely within the district court's discretion. *See Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1171 (Fed. Cir. 2006)*. The district court was ultimately undisturbed by the Taniguchi/Miyazawa communication based on its evaluation of the witness testimony presented, and this court sees no abuse of discretion. These facts certainly do not rise to the level of "culpability" this court required in *Kingsdown, 863 F.2d at 876*, to establish intent to deceive, or even gross negligence.

Finally, the district court found that Teva's theory that Eisai deliberately hid the ball from the Patent Office by separately filing the '552 and '013 prosecutions to be "implausibly risky," given that such similar applications would usually be assigned to the same examiner in the same art unit. *Trial Order at 53*. The district court thus had ample bases from which to conclude that Eisai's failure to disclose its co-pending '013 application along with the rejections issued in its prosecution, while not completely forthcoming, did not rise to the level of inequitable conduct.

With respect to the Byk Gulden patent, Teva and Dr. Reddy's argue that Eisai's failure to disclose **[**18]** this reference to the Patent Office during prosecution of the *'552 patent* was material because a reasonable examiner would have used it to issue a new and stronger prima facie obviousness rejection on the basis of Byk Gulden's disclosure of asymmetrically-substituted compounds having a methoxyethoxy at the 4-position of the pyridine ring. But the district court found Byk Gulden's teachings cumulative with references already disclosed to the Patent Office (Junggren or Junggren combined with Beecham). As per *37 C.F.R. § 1.56*, cumulative evidence is definitionally *not* material evidence. *See Monsanto Co. v. Bayer Bioscience N.V., 514 F.3d 1229, 1237 (Fed. Cir. 2008)*. Here, the Junggren reference specifically disclosed asymmetrically substituted compounds, including a compound having a 4-position methoxyethoxy

substituent. Thus the Byk Gulden reference offered nothing new to the record already before the Patent Office. And even Teva's expert conceded Byk Gulden would not have provided the examiner with anything new. *Id. at 57*. Thus the district court was well within its discretion in concluding that the Byk Gulden patent was not material to the prosecution of the *'552 patent*. Even if Byk **[**19]** Gulden had been material, the lack of clear and convincing evidence of intent to deceive would nonetheless have imposed an insurmountable bar to finding inequitable conduct, for the reasons given by the district court.

As for the Fujisaki Declaration, Eisai submitted it during prosecution to overcome an obviousness rejection. Because this reference shows rabeprazole's pharmacological properties, the trial court found it highly material. *Id. at 59*. Teva **[*1362]** and Dr. Reddy's argue that the data presented in the Fujisaki Declaration were misleading. They contend that the comparison with two non-prior art compounds without a comparison of the ethyl homolog of rabeprazole, SHKA 661, sent the examiner on a dead-end side trip. The district court properly characterized this argument as "contorted." *Id.* The Fujisaki Declaration indisputably showed a comparison between rabeprazole and the prior art compound called out by the examiner, demonstrating rabeprazole's superiority. Further, as discussed above, the materiality of SHKA 661 and the patent application claiming it was low. The data from the Fujisaki Declaration were relevant to prosecution, but Eisai had no obligation to include additional, unnecessary **[**20]** data such as a comparison to SHKA 661. Thus the district court did not abuse its discretion in concluding that Eisai did not commit inequitable conduct in failing to include additional data in the Fujisaki Declaration to the examiner. Even here, where the submission to the Patent Office itself was highly material to prosecution, the lack of deceptive intent rendered stillborn yet another allegation of inequitable conduct.

Finally, Teva and Dr. Reddy's assert that that Eisai deceptively declined to inform the examiner of a patent application for lansoprazole, a prior art proton pump inhibitor (and the active ingredient in Prevacid). The district court disposed of this argument on summary judgment. The district court found that Teva and Dr. Reddy's had presented neither direct evidence of deceptive intent nor any evidence to support an inference of materiality. *SJ Enforceability Order, 472 F. Supp. 2d 493, [slip op.]at 58*. The strongest evidence of some problem was the passing comment of one Eisai "insider" that the similarity of lansoprazole and rabeprazole "bothers me." *472 F. Supp. 2d 493 at *526*. But this vague, subjective statement is not sufficient by any means to establish materiality, let alone intent. Moreover, given lansoprazole's **[**21]** fluorinated substituent and its resultant impotence to render the *'552 patent* invalid, the district court properly rejected this strained theory of inequitable conduct on summary judgment.

IV

In a series of thoughtful, thorough opinions, the district court carefully explained its reasoning with respect to both obviousness and inequitable conduct. Because the district court properly concluded that Teva and Dr. Reddy's failed to prove that the *'552 patent* was invalid for obviousness or unenforceable for inequitable conduct, this court affirms the district court's judgment.

*AFFIRMED*

COSTS

Each party shall bear its own costs.

LEXSEE 16 F.3D 380

**IN RE BRIAN W. BAIRD, ART F. DIAZ, WILLIAM H. DICKSTEIN and CHARLES M. SEYMOUR**

**93-1262**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***16 F.3d 380*; *1994 U.S. App. LEXIS 1114*; *29 U.S.P.Q.2D (BNA) 1550***

**January 19, 1994, Decided**

**PRIOR HISTORY:** [**1] Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences. Serial No. 07/333,524

**DISPOSITION:** REVERSED

**COUNSEL:** John A. Brady, Lexmark International, Inc., of Lexington, Kentucky, argued for appellant.

Adriene B. Lepiane, Assistant Solicitor, Office of the Solicitor, of Arlington, Virginia, argued for appellee. With her on the brief were Fred E. McKelvey, Solicitor and Richard E. Schafer, Associate Solicitor.

**JUDGES:** Before MICHEL, PLAGER and LOURIE, Circuit Judges.

**OPINION BY:** LOURIE

**OPINION**

[*381] LOURIE, *Circuit Judge.*

Applicants Brian W. Baird, Art F. Diaz, William H. Dickstein, and Charles M. Seymour (collectively Baird) [1] appeal from the October 15, 1992 decision of the U.S. Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences, Appeal No. 92-0860, affirming the examiner's final rejection of claims 1-5 of application Serial No. 07/333,524, entitled "Flash Fusible Toner Resins," as unpatentable on the ground of obviousness under *35 U.S.C. § 103 (1988)*. We reverse.

1 The real party in interest is Lexmark International, Inc.

[**2] BACKGROUND

Baird's application is directed to a flash fusible toner comprising a polyester of bisphenol A and an aliphatic dicarboxylic acid. Synthesis of the toner compositions involves the acetylation of bisphenol A and the reaction of that product with an aliphatic dicarboxylic acid selected from the group consisting of succinic acid, glutaric acid, and adipic acid. The application discloses that toners containing bisphenol A have optimal characteristics for flash fusing including, *inter alia,* high thermal stability and low critical surface energy.

Claim 1, the only claim at issue, reads as follows:

> 1. A flash fusible toner comprising a binder resin which is a bisphenol A polyester containing an aliphatic dicarboxylic acid selected from the group consisting of succinic acid, glutaric acid and adipic acid.

Claim 1 stands rejected as obvious over U.S. Patent 4,634,649 to Knapp et al., which relates to developer compositions comprised of, *inter alia,* the polymeric esterification product of a dicarboxylic acid and a diphenol of the following generic formula:

[SEE DIAGRAM IN ORIGINAL]

> wherein R is selected from substituted and unsubstituted alkylene radicals having [**3] from about 2 to about 12 carbon atoms, alkylidene radicals having from 1 to 12 carbon atoms and cycloalkylidene radicals having from 3 to 12 carbons atoms; R' and R" are selected from substituted and unsubstituted alkylene radicals having from 2 to 12 carbon atoms, alkylene arylene radicals having from 8 to 12 carbon atoms and arylene radicals; X and X' are selected from hydrogen or an alkyl radical having from 1 to 4 carbon atoms; and each n is a number from 0 (zero) to 4

Col. 4, lines 16-38. The Knapp formula contains a broad range of variables and thus encompasses a large number of different diphenols, one of which is bisphenol A, which is shown in Baird's application as having the following structure:

[SEE DIAGRAM IN ORIGINAL]

Knapp also discloses that the dicarboxylic acids have the general formula:

HOOCR"'n[3]COOH

> [*382] wherein R"' is a substituted or unsubstituted alkylene radical having from 1 to 12 carbon atoms, arylene radicals or alkylene arylene radicals having from 10 to 12 carbon atoms and n[3] is a number of less than 2.

Col. 5, lines 6-14. Twenty typical dicarboxylic acids are recited, including succinic acid, glutaric acid, and adipic acid, the dicarboxylic [**4] acids recited in claim 1.

The examiner rejected claim 1 as obvious on the ground that Knapp Specifically discloses as components of his esters the three dicarboxylic acids recited in claim 1 and a generic formula which encompasses bisphenol A. Recognizing that bisphenol A is defined when certain specific variables are chosen, the examiner reasoned that bisphenol A "may be easily derived from the generic formula of the diphenol in [Knapp] and all the motivation the worker of ordinary skill in the art needs to arrive at the particular polyester of the instant claim[] is to follow [that formula]."

The Board upheld the examiner's rejection. It rejected Baird's argument that there was no motivation for one to select bisphenol A from Knapp and summarily concluded that "the fact that [the claimed] binder resin is clearly encompassed by the generic disclosure of Knapp . . . provides ample motivation for the selection of [the claimed composition]." Slip op. at 3. The Board's decision was affirmed on reconsideration.

DISCUSSION

The only issue before us is whether the record supports the Board's conclusion that, in view of the teachings of Knapp, the claimed compounds [2] would have been obvious [**5] to one of ordinary skill in the art. We review an obviousness determination by the Board de *novo*, while we review underlying factual findings for clear error. *In re Beattie, 974 F.2d 1309, 1311, 24 U.S.P.Q.2D (BNA) 1040, 1041 (Fed. Cir. 1992).*

> 2 Since the toner, the resin, and the polyester compounds appear to be treated in the Board opinion and patent application as synonymous, and the PTO has premised its obviousness rejection on the obviousness of the compounds, we will treat this case accordingly.

Baird does not dispute the fact that the generic diphenol formula of Knapp encompasses bisphenol A. Nor does Baird dispute that Knapp specifically discloses the three dicarboxylic acids recited in claim 1. Rather, Baird argues that there is no suggestion in Knapp to select bisphenol A from the vast number of diphenols covered by the generic formula and that the Board thus erred in concluding that the claimed compounds would have been obvious.

What a reference teaches is a question [**6] of fact. *Beattie, 974 F.2d at 1311, 24 U.S.P.Q.2D (BNA) at 1041.* The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious. *In re Jones, 958 F.2d 347, 350, 21 U.S.P.Q.2D (BNA) 1941, 1943 (Fed. Cir. 1992)* (rejecting Commissioner's argument that "regardless [] how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it"). *Jones* involved an obviousness rejection of a claim to a specific compound, the 2-(2'-aminoethoxy)ethanol salt of 2-methoxy-3,6-dichlorobenzoic acid (dicamba), as

obvious in view of, *inter alia,* a prior art reference disclosing a genus which admittedly encompassed the claimed salt. We reversed the Board's rejection, reasoning that the prior art reference encompassed a "potentially infinite genus" of salts of dicamba and listed several such salts, but that it did not disclose or suggest the claimed salt. *Id.*

In the instant case, the generic diphenol formula disclosed in Knapp contains a large number of variables, and we estimate that it encompasses more than 100 million [**7] different diphenols, only one of which is bisphenol A. While the Knapp formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables. Indeed, Knapp appears to teach away from the selection of bisphenol A by focusing on more complex diphenols, including 2,2-bis(4-beta-hydroxyethoxyphenyl)propane, 2,2-bis(4-hydroxypropoxyphenyl)propane, and 2,2-bis(4-hydroxyisopropoxyphenyl)propane. Col. 4, lines 51-64. Knapp teaches that in preferred diphenols, R [*383] has 2 to 4 carbon atoms and R' and R" have 3 to 4 carbon atoms, and in "optimum" diphenols, R is an isopropylidene radical, R' and R" are selected from the group consisting of propylene and butylene radicals, and n is one. Col. 4, lines 38-47. Knapp further states that the diphenol in the preferred polyester material is 2,2-bis(4-hydroxyisopropoxyphenyl)propane. Col. 5, lines 36-38. Fifteen typical diphenols are recited. None of them, or any of the other preferred phenols recited above, is or suggests bisphenol A.

The Commissioner repeatedly emphasizes that many of the diphenols specifically enumerated in Knapp are derivatives of [**8] bisphenol A. He argues that Knapp thus suggests the selection of bisphenol A itself. We disagree, because, according to the specification, the diphenol in the esters of claim 1 can only be bisphenol A, not a bisphenol A derivative. While Knapp may suggest certain complex bisphenol A derivatives, it does not describe or suggest bisphenol A and therefore does not motivate the selection of bisphenol A.

"[A] reference must be considered not only for what it expressly teaches, but also for what it fairly suggests." *In re Burckel, 592 F.2d 1175, 1179, 201 U.S.P.Q. (BNA) 67, 70 (CCPA 1979).* Given the vast number of diphenols encompassed by the generic diphenol formula in Knapp, and the fact that the diphenols that Knapp specifically discloses to be "typical," "preferred," and "optimum" are different from and more complex than bisphenol A, we conclude that Knapp does not teach or fairly suggest the selection of bisphenol A. *See In re Bell, 991 F.2d 781, 26 U.S.P.Q.2D (BNA) 1529 (Fed. Cir. 1993)* (DNA sequence would not have been obvious in view of prior art reference suggesting a nearly infinite number of possibilities [**9] and failing to suggest why among all those possibilities one would seek the claimed sequence). A disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.

CONCLUSION

The Board clearly erred in finding that Knapp would have provided the requisite motivation for the selection of bisphenol A in the preparation of the claimed compounds. Accordingly, the decision of the Board affirming the rejection of claim 1 as obvious over Knapp is reversed.

COSTS

No costs.

*REVERSED*

LEXSEE 958 F.2D 347

**IN RE RITA S. JONES, MICHAEL T. CHIRCHIRILLO and JOHNNY L. BURNS**

**91-1380**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

*958 F.2d 347; 1992 U.S. App. LEXIS 2752; 21 U.S.P.Q.2D (BNA) 1941*

**February 28, 1992, Decided**

**SUBSEQUENT HISTORY:** As Corrected March 5, 1992.

**PRIOR HISTORY:** **[**1]** Appeal from: U.S. Patent & Trademark Office, Board of Patent Appeals & Interferences

**DISPOSITION:** REVERSED.

**COUNSEL:** Melvyn M. Kassenoff, Sandoz Corporation Patent & Trademark Dept., of East Hanover, New Jersey, argued for appellant. With him on the brief were Gerald D. Sharkin and Richard E. Vila. Also on the brief was Joanne M. Giesser, of Palo Alto, California.

Harris A. Pitlock, Associate Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief was Fred E. McKelvey, Solicitor. Of counsel was Richard E. Schafer, Patent & Trademark Office.

**JUDGES:** Before RICH, ARCHER, and CLEVENGER, Circuit Judges.

**OPINION BY:** RICH

**OPINION**

**[*348]** RICH, *Circuit Judge*.

Rita S. Jones et al. (collectively Jones) appeal from the April 15, 1991 decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), Appeal No. 90-1920, sustaining the rejection of claim 1, the only claim of application Ser. No. 07/099,279, titled "The 2-(2'-Aminoethoxy)Ethanol Salt of Dicamba," as unpatentable under *35 USC 103*. We conclude that the PTO has not presented a *prima facie* case of obviousness, and therefore *reverse*.

*The Invention*

The claimed invention is a novel salt of 2-methoxy-3,6-dichlorobenzoic acid, **[**2]** which acid is commonly referred to as "dicamba." A known herbicide, dicamba has typically been sold in the form of its known dimethylamine salt.

The sole claim of the application on appeal reads:

1. The 2-(2'-aminoethoxy)ethanol salt of dicamba.

The claimed salt has the following structure:

[SEE STRUCTURE ILLUSTRATION IN ORIGINAL]

**[*349]** *The Rejection*

Claim 1 stands rejected as obvious in view of the combined teachings of the following references:

| Richter | U.S. Patent No. 3,013,054 | Dec. 12, 1961 |
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|---|---|---|
| Moyle et al. | U.S. Patent No. 3,056,669 | Oct. 2, 1962 |
| Balassa | U.S. Patent No. 3,725,031 | Apr. 3, 1973 |
| Zorayan et al. | 88 Chem. Abstracts No. 52300j | 1978 |
| Wideman | 86 Chem. Abstracts No. 43711a | 1977 |

Richter, which all agree is the closest prior art, discloses dicamba in free acid, ester, and salt forms, for use as a herbicide. Among the salt forms disclosed are substituted ammonium salts, a genus which admittedly encompasses the claimed salt. Richter does not specifically disclose the claimed 2-(2'-aminoethoxy)ethanol salt, however. Most notably, Richter discloses (emphasis and bracketed word ours):

Compositions in which X is substituted ammonium are amine salts of 2-methoxy-3,6-dichlorobenzoic **[**3]** acid [dicamba] and are prepared by the addition of the free acid to various amines. Typical amines which can be used to prepare such amine salts are dimethylamine, trimethylamine, triethylamine, diethanolamine, triethanolamine, isopropylamine, morpholine, and the like. *The resulting products are, respectively the dimethylamino, trimethylamino, triethylamino, diethanolamino, triethanolamino, isopropylamino, and morpholino salts of 2-methoxy-3,6-dichlorobenzoic acid.*

Zorayan teaches the amine (H[2]N(CH[2]CH[2]O)[2]H) used to make the claimed salt, as well as the use of that amine in the preparation of surfactants for shampoos, bath preparations, and emulsifiers.

Wideman also teaches the amine disclosed in Zorayan.

The content of the remaining references is unnecessary to our decision.

The Board upheld the examiner's rejection of claim 1 as obvious, finding that the claimed 2-(2'-aminoethoxy)ethanol salt of dicamba and the diethanolamine salt of dicamba specifically disclosed by Richter were "closely related in structure," and that based upon the expectation that "compounds similar in structure will have similar properties," a *prima facie* case of obviousness had arisen. The Board **[**4]** found that Jones' rebuttal evidence (Rule 132 declarations and data reported in the specification) failed to "compare the claimed subject matter with the closest prior art," and accordingly did not serve to rebut the *prima facie* case. This appeal followed.

*Analysis*

The Solicitor contends that the claimed salt falls within the genus of substituted amine salts of dicamba disclosed by Richter, and that, like Richter's genus, the claimed compound has herbicidal activity. Thus, the Solicitor urges, under the circumstances of this case, (1) the genus/species relationship and (2) the common utility of the claimed and prior art compounds support the Board's holding of *prima facie* obviousness. Moreover, the Solicitor adds, although the claimed compound is neither a homolog nor a position isomer of those salts specifically disclosed in Richter, it is structurally similar thereto, particularly the diethanolamino salt noted by the Board.

The question of "structural similarity" in chemical patent cases has generated a body of patent law unto itself. [1] Particular types **[*350]** or categories of structural similarity without more have, in past cases, given rise to *prima facie* obviousness; **[**5]** *see, e.g., In re Dillon, 919 F.2d 688, 692-94, 16 USPQ2d 1897, 1900-02 (Fed. Cir. 1990)* (tri-orthoesters and tetra-orthoesters), *cert. denied, U.S. , 111 S. Ct. 1682 (1991)*; *In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978)* (stereoisomers); *In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)* (adjacent homologs and structural isomers); *In re Hoch, 57 C.C.P.A. 1292, 428 F.2d 1341, 166 USPQ 406 (CCPA 1970)* (acid and ethyl ester). However, none of these types of structural similarity are involved here. And in any event, this court has previously stated that generalization is to be avoided insofar as specific structures are alleged to be *prima facie* obvious one from the other. *In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 872 (Fed. Cir. 1985).*

1 *See generally* Helmuth A. Wegner, "Prima Facie Obviousness of Chemical Compounds," 6 *Am. Pat. L. Assoc. Q. J.* 271 (1978).

[**6] On the basis of the record before us, we cannot sustain the Board's conclusion that the claimed salt and the diethanolamino salt disclosed by Richter are so "closely related in structure" as to render the former *prima facie* obvious in view of the latter. The claimed salt is a primary amine with an ether linkage. The diethanolamino salt disclosed by Richter is a secondary amine, without an ether linkage:

[SEE ILLUSTRATION IN ORIGINAL]

In addition, the only substituted ammonium salt of dicamba expressly disclosed by Richter having an ether linkage is the morpholino salt, which is *cyclic* in structure:

[SEE STRUCTURE ILLUSTRATION IN ORIGINAL]

The claimed salt is, plainly, acyclic; i.e., linear. Lastly, while the isopropylamino salt disclosed by Richter is a primary amine, as is the claimed salt, its iso-structure is quite different:

[SEE STRUCTURE ILLUSTRATION IN ORIGINAL]

The lack of close similarity of structure is not negated by the fact that the claimed salt is a member of Richter's broadly disclosed genus of substituted ammonium salts of dicamba. The Solicitor contends that "the relative size of the genus disclosed by the prior art would not appear to be a controlling [**7] factor in determining whether a *prima facie* case of obviousness exists for a species encompassed within the described genus," citing *Merck & Co. v. Biocraft Labs., Inc., 874 F.2d 804, 806-09, 10 USPQ2d 1843, 1845-48* (Fed. Cir.), *cert. denied, 493 U.S. 975, 110 S. Ct. 498, 107 L. Ed. 2d 502, 110 S. Ct. 498 (1989)*. We decline to extract from *Merck* the rule that the Solicitor appears to suggest--that regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it. In *Merck*, at issue on appeal was whether claims to a composition of two diuretics, amiloride and hydrochlorothiazide, present in a particular "medically synergistic" weight ratio, would have been obvious in view of a specific prior art disclosure of amiloride in combination with hydrochlorothiazide, one of 1200 such combinations disclosed in the prior art reference. *Id. at 806, 10 USPQ2d at 1845*. Based on the facts before it, including evidence at trial that the experimentation needed to arrive at the claimed dosage was "nothing more than routine," *id. at 809, 10 USPQ2d at 1847*, [**8] the court held that the claimed invention would have been obvious. In contrast, though Richter discloses the potentially infinite genus of "substituted ammonium salts" of dicamba, and lists several such salts, the salt claimed here is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it *prima facie* obvious. Every case, particularly those raising the issue of obviousness under *section 103*, must necessarily be decided upon its own facts.

[*351] The Solicitor points out that, given the breadth of forms of dicamba (free acid, ester, or salt) disclosed by Richter as having herbicidal utility, one of ordinary skill in the art would appreciate that the dicamba group has significance with respect to imparting herbicidal activity to dicamba compounds. Thus, the Solicitor contends, one skilled in the art would have been motivated to use, with dicamba, substituted ammonium salts made from a known amine, such as the amine disclosed by Zorayan and Wideman, and would have expected such a salt to have herbicidal activity. Before the PTO may combine the disclosures of two or more [**9] prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988)*. We see no such suggestion in Zorayan, which is directed to shampoo additives, nor in Wideman, which teaches that the amine used to make the claimed compound is a byproduct of the production of morpholine. Nor does the broad disclosure of Richter fill the gap, for the reasons discussed above.

Conspicuously missing from this record is any *evidence,* other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed 2-(2'-aminoethoxy)ethanol salt. *See Grabiak, 769 F.2d at 731-32, 226 USPQ at 872* ("In the case before us there must be adequate support in the prior art for the [prior art] ester/[claimed] thioester change in structure, in order to complete the PTO's *prima* [**10] *facie* case and shift the burden of going forward to the applicant."); *In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed.*

*Cir. 1984)* ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.")

*Conclusion*

We conclude that the PTO did not establish a *prima facie* case of obviousness, and thus did not shift to Jones the burden of coming forward with unexpected results or other objective evidence of non-obviousness. Accordingly, the decision of the Board is

*REVERSED.*

LEXSEE 83 U.S.P.Q.2D 1169

**TAKEDA CHEMICAL INDUSTRIES, LTD. and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., Plaintiffs-Appellees, v. ALPHAPHARM PTY., LTD. and GENPHARM, INC., Defendants-Appellants.**

**06-1329**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***492 F.3d 1350*; *2007 U.S. App. LEXIS 15349*; *83 U.S.P.Q.2D (BNA) 1169***

**June 28, 2007, Decided**

**SUBSEQUENT HISTORY:** Later proceeding at *Takeda Chem. Indus. v. Ranbaxy Labs., Ltd., 2007 U.S. App. LEXIS 15883 (Fed. Cir., June 28, 2007)*
US Supreme Court certiorari denied by Alphapharm Pty v. Takeda Chem. Indus., 2008 U.S. LEXIS 3015 (U.S., Mar. 31, 2008)

**PRIOR HISTORY: [**1]**
Appealed from: United States District Court for the Southern District of New York Judge Denise Cote.
*Takeda Chem. Indus. v. Mylan Labs., Inc., 417 F. Supp. 2d 341, 2006 U.S. Dist. LEXIS 6710 (S.D.N.Y., 2006)*

**DISPOSITION:** AFFIRMED.

**COUNSEL:** David G. Conlin, Edwards Angell Palmer & Dodge LLP, of Boston, Massachusetts, argued for plaintiffs-appellees. With him on the brief were Barbara L. Moore, Kathleen B. Carr, and Adam P. Samansky; and Anthony J. Viola, of New York, New York. Of counsel on the brief was Mark Chao, Takeda Pharmaceuticals North America, Inc., of Lincolnshire, Illinois.

Kevin F. Murphy, Frommer Lawrence & Haug LLP, of New York, New York, argued for defendants-appellants. With him on the brief were Edgar H. Haug and Jeffrey A. Hovden.

**JUDGES:** Before LOURIE, BRYSON, and DYK, Circuit Judges. Opinion for the court filed by Circuit Judge LOURIE. Concurring opinion filed by Circuit Judge DYK. DYK, Circuit Judge, concurring.

**OPINION BY:** LOURIE

**OPINION**

**[*1352]** LOURIE, *Circuit Judge*.

Alphapharm Pty., Ltd. and Genpharm, Inc. (collectively "Alphapharm") appeal from the decision of the United States District Court for the Southern District of New York, following a bench trial, that *U.S. Patent 4,687,777* was not shown to be invalid under *35 U.S.C. § 103*. *Takeda Chem. Indus., Ltd. v. Mylan Labs., 417 F. Supp. 2d 341 (S.D.N.Y. 2006)*. Because we conclude **[**2]** that the district court did not err in determining that the claimed compounds would not have been obvious in light of the prior art, and hence that the patent has not been shown to be invalid, we affirm.

BACKGROUND

Diabetes is a disease that is characterized by the body's inability to regulate blood sugar. It is generally caused by inadequate levels of insulin--a hormone produced in the pancreas. Insulin allows blood sugar or glucose, which is derived from food, to enter into the body's cells and be converted into energy. There are two types of diabetes, known as Type 1 and Type 2. In Type 1 diabetes, the pancreas fails to produce insulin, and individuals suffering from this type of diabetes must regularly receive insulin from an external source. In

contrast, Type 2 diabetic individuals produce insulin. However, their bodies are unable to effectively use the insulin that is produced. This is also referred to as insulin resistance. As a result, glucose is unable to enter the cells, thereby depriving the body of its main source of energy. Type 2 diabetes is the most common form of diabetes--affecting over 90% of diabetic individuals.

In the 1990s, a class of drugs known as thiazolidinediones **[**3]** ("TZDs") was introduced on the market as a treatment for Type 2 diabetes. Takeda Chemical Industries, Ltd., and Takeda Pharmaceuticals North America, Inc. (collectively "Takeda") first invented certain TZDs in the 1970s. Takeda's research revealed that TZDs acted as insulin sensitizers, *i.e.*, compounds that ameliorate insulin resistance. Although the function of TZDs was not completely understood, TZDs appeared to lower blood glucose levels by binding to a molecule in the nucleus of the cell known as PPAR-gamma, which activates insulin receptors and stimulates the production of glucose transporters. *Takeda, 417 F. Supp. 2d at 348-49*. The transporters then travel to the cellular surface and enable glucose to enter the cell from the bloodstream. *Id.*

Takeda developed the drug ACTOS (R), which is used to control blood sugar in patients who suffer from Type 2 diabetes. ACTOS (R) has enjoyed substantial commercial success since its launch in 1999. By **[*1353]** 2003, it held 47% of the TZD market, and gross sales for that year exceeded $ 1.7 billion. *Id. at 386*. The active ingredient in ACTOS (R) is the TZD compound pioglitazone, a compound claimed in the patent in suit.

Takeda owns *U.S. Patent 4,687,777* **[**4]** (the "*'777 patent*") entitled "Thiazolidinedione Derivatives, Useful As Antidiabetic Agents." The patent is directed to "compounds which can be practically used as antidiabetic agents having a broad safety margin between pharmacological effect and toxicity or unfavorable side reactions." *'777 patent* col.1 ll.34-37. The asserted claims are claims 1, 2, and 5. Claim 1 claims a genus of compounds. Claim 5 claims pharmaceutical compositions containing that genus of compounds. Those claims read as follows:

> 1. A compound of the formula:
>
> [SEE DIAGRAM IN ORIGINAL]
>
> or a pharmacologically acceptable salt thereof.
>
> 5. An antidiabetic composition which consists essentially of a compound of the formula:
>
> [SEE DIAGRAM IN ORIGINAL]
>
> or a pharmacologically acceptable salt thereof, in association with a pharmacologically acceptable carrier, excipient or diluent.

*Id.*, claims 1 & 5.

For purposes of this appeal, the critical portion of the compound structure is the left moiety of the molecule, namely, the ethyl-substituted pyridyl ring. [1] That chemical structure, which has an ethyl substituent (C[2]H[5]) pictorially drawn to the center of the pyridyl ring, indicates that the structure covers four possible compounds, **[**5]** *viz.*, compounds with an ethyl substituent located at the four available positions on the pyridyl ring. *Takeda, 417 F. Supp. 2d at 360*. The formula includes the 3-ethyl compound, 4-ethyl compound, 5-ethyl compound (pioglitazone), and 6-ethyl compound.

**[*1354]** Claim 2 of the *'777 patent* covers the single compound pioglitazone. That claim, which depends from claim 1, reads:

> 2. A compound as claimed in claim 1, wherein the compound is 5-4-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl-2,4-thiazolidinedione.

*'777 patent*, claim 2. Pioglitazone is referred to as the 5-ethyl compound because the ethyl substituent is attached to the 5-position on the pyridyl ring. That portion of the compound is depicted as:

[SEE DIAGRAM IN ORIGINAL]

1 Pyridine is a "six-membered carbon-containing ring with one carbon replaced by a nitrogen." *Takeda, 417 F. Supp. 2d at 351*.

Alphapharm, a generic drug manufacturer, filed an Abbreviated New Drug Application ("ANDA") pursuant to the Hatch-Waxman Act seeking U.S. Food and Drug Administration ("FDA") approval under *21 U.S.C. §*

*355(j) et seq.* to manufacture and sell a generic version of pioglitazone. Alphapharm filed a Paragraph IV certification with its ANDA pursuant to § 505(j)(2)(B)(ii), [**6] asserting that the *'777 patent* is invalid as obvious under *35 U.S.C. § 103*. In response, Takeda sued Alphapharm, along with three other generic drug manufacturers who also sought FDA approval to market generic pioglitazone, alleging that the defendants have infringed or will infringe the *'777 patent*.

On January 17, 2006, the district court commenced a bench trial solely on the issues of validity and enforceability of the *'777 patent*. Alphapharm advanced its invalidity argument, asserting that the claimed compounds would have been obvious at the time of the alleged invention. Alphapharm's obviousness contention rested entirely on a prior art TZD compound that is referenced in Table 1 of the *'777 patent* as compound b. The left moiety of compound b consists of a pyridyl ring with a methyl (CH[3]) group attached to the 6-position of the ring. That portion of its chemical structure is illustrated as follows:

[SEE DIAGRAM IN ORIGINAL]

Alphapharm asserted that the claimed compounds would have been obvious over compound b.

The district court found that Alphapharm failed to prove by clear and convincing evidence that the asserted claims were invalid as obvious under *35 U.S.C. § 103*. The court first [**7] concluded that there was no motivation in the prior art to select compound b as the lead compound for antidiabetic research, and that the prior art taught away from its use. As such, the court concluded that Alphapharm failed to make a prima facie case of obviousness. The court continued its analysis and found that even if Alphapharm succeeded in making a prima facie showing, Takeda would still prevail because any prima facie case of obviousness was rebutted by the unexpected results of pioglitazone's nontoxicity. The court then rendered judgment in favor of Takeda. The district court also held that the *'777 patent* had not been procured though inequitable conduct. That decision has been separately appealed and has been affirmed in a decision issued today.

Alphapharm timely appealed. We have jurisdiction pursuant to *28 U.S.C. § 1295(a)(1)*.

DISCUSSION

*A. Standard of Review*

In this appeal, we are presented with one issue, namely, whether the asserted [*1355] claims of the *'777 patent* would have been obvious under *35 U.S.C. § 103* at the time the invention was made. An invention is not patentable, *inter alia*, "if the differences between the subject matter sought to be patented and the prior art are [**8] such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *35 U.S.C. § 103(a)*. Because a patent is presumed to be valid, *35 U.S.C. § 282*, the evidentiary burden to show facts supporting a conclusion of invalidity, which rests on the accused infringer, is one of clear and convincing evidence. *AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003)*. Whether an invention would have been obvious under *35 U.S.C. § 103* is a "question of law, reviewed de novo, based upon underlying factual questions which are reviewed for clear error following a bench trial." *Alza Corp. v. Mylan Labs., Inc., 464 F.3d 1286, 1289 (Fed. Cir. 2006)*.

*B. Obviousness*

Alphapharm raises three main arguments in support of its contention that the claims would have been obvious. First, Alphapharm asserts that the district court misapplied the law, particularly the law governing obviousness in the context of structurally similar chemical compounds. According to Alphapharm, the record established that compound b was the most effective antidiabetic compound in the prior art, and thus the court erred by failing to apply [**9] a presumption that one of ordinary skill in the art would have been motivated to make the claimed compounds. Alphapharm asserts that such a conclusion is mandated by our case law, including our en banc decision in *In re Dillon, 919 F.2d 688 (Fed. Cir. 1990)*. Second, Alphapharm argues that the court erred in determining the scope and content of the prior art, in particular, whether to include the prosecution history of the prior *'779 patent*. Lastly, Alphapharm assigns error to numerous legal and factual determinations and certain evidentiary rulings that the court made during the course of the trial.

Takeda responds that the district court correctly determined that Alphapharm failed to prove by clear and convincing evidence that the asserted claims are invalid as obvious. Takeda contends that there was overwhelming evidence presented at trial to support the

court's conclusion that no motivation existed in the prior art for one of ordinary skill in the art to select compound b as a lead compound, and even if there was, that the unexpected results of pioglitazone's improved toxicity would have rebutted any prima facie showing of obviousness. Takeda further argues that all of Alphapharm's **[**10]** remaining challenges to the district court's legal and factual rulings are simply without merit.

We agree with Takeda that the district court did not err in concluding that the asserted claims of the '777 *patent* would not have been obvious. The Supreme Court recently addressed the issue of obviousness in *KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007)*. The Court stated that the *Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966)*, factors still control an obviousness inquiry. Those factors are: 1) "the scope and content of the prior art"; 2) the "differences between the prior art and the claims"; 3) "the level of ordinary skill in the pertinent art"; and 4) objective evidence of nonobviousness. *KSR, 127 S. Ct. at 1734* (quoting *Graham, 383 U.S. at 17-18*).

In a thorough and well-reasoned opinion, albeit rendered before *KSR* was decided **[*1356]** by the Supreme Court, the district court made extensive findings of fact and conclusions of law as to the four *Graham* factors. Alphapharm's arguments challenge the court's determinations with respect to certain of these factors, which we now address.

*1. Differences Between the Prior Art and the Claims*

*a. Selection of Compound b as Lead* **[**11]** *Compound*

Alphapharm's first argument challenges the court's determination with regard to the "differences between the prior art and the claims." Alphapharm contends that the court erred as a matter of law in holding that the ethyl-substituted TZDs were nonobvious in light of the closest prior art compound, compound b, by misapplying the law relating to obviousness of chemical compounds.

We disagree. Our case law concerning prima facie obviousness of structurally similar compounds is well-established. We have held that "structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness." *Dillon, 919 F.2d at 692*. In addition to structural similarity between the compounds, a prima facie case of obviousness also requires a showing of "adequate support in the prior art" for the change in structure. *In re Grabiak, 769 F.2d 729, 731-32 (Fed. Cir. 1985)*.

We elaborated on this requirement in the case of *In re Deuel, 51 F.3d 1552, 1558 (Fed. Cir. 1995)*, where we stated that "[n]ormally a prima facie case of obviousness is based **[**12]** upon structural similarity, *i.e.*, an established structural relationship between a prior art compound and the claimed compound." That is so because close or established "[s]tructural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds." *Id.* A known compound may suggest its homolog, analog, or isomer because such compounds "often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." *Id.* We clarified, however, that in order to find a prima facie case of unpatentability in such instances, a showing that the "prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention" was also required. *Id.* (citing *In re Jones, 958 F.2d 347 (Fed. Cir. 1992)*; *Dillon, 919 F.2d 688*; *Grabiak, 769 F.2d 729*; *In re Lalu, 747 F.2d 703 (Fed. Cir. 1984)*).

That test for prima facie obviousness for chemical compounds is consistent with the legal principles enunciated in *KSR*. [2] While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test in an obviousness **[**13]** inquiry, the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine **[*1357]** the elements in the way the claimed new invention does" in an obviousness determination. *KSR, 127 S. Ct. at 1731*. Moreover, the Court indicated that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* As long as the test is not applied as a "rigid and mandatory" formula, that test can provide "helpful insight" to an obviousness inquiry. *Id.* Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound.

2 We note that the Supreme Court in its *KSR* opinion referred to the issue as whether claimed subject matter "was" or "was not" obvious. Since *35 U.S.C. § 103* uses the language "would have been obvious," and the Supreme Court in *KSR* did consider the particular time at which obviousness is determined, we consider that the Court did not in *KSR* reject the standard statutory formulation of the inquiry whether **[**14]** the claimed subject matter "would have been obvious at the time the invention was made." *35 U.S.C. § 103*. Hence, we will continue to use the statutory "would have been" language.

We agree with Takeda and the district court that Alphapharm failed to make that showing here. Alphapharm argues that the prior art would have led one of ordinary skill in the art to select compound b as a lead compound. By "lead compound," we understand Alphapharm to refer to a compound in the prior art that would be most promising to modify in order to improve upon its antidiabetic activity and obtain a compound with better activity. [3] Upon selecting that compound for antidiabetic research, Alphapharm asserts that one of ordinary skill in the art would have made two obvious chemical changes: first, homologation, *i.e.*, replacing the methyl group with an ethyl group, which would have resulted in a 6-ethyl compound; and second, "ring-walking," or moving the ethyl substituent to another position on the ring, the 5-position, thereby leading to the discovery of pioglitazone. Thus, Alphapharm's obviousness argument clearly depends on a preliminary finding that one of ordinary skill in the art would have selected **[**15]** compound b as a lead compound.

3 The parties do not dispute that compound b was the closest prior art compound. Thus, the legal question is whether or not the claimed subject matter would have been obvious over that compound. We will, however, use Alphapharm's terminology of "lead compound" in this opinion, deciding the appeal as it has been argued.

The district court found, however, that one of ordinary skill in the art would not have selected compound b as the lead compound. In reaching its determination, the court first considered Takeda's *U.S. Patent 4,287,200* (the "*'200 patent*"), which was issued on September 1, 1981, and its prosecution history. The court found that the *'200 patent* "discloses hundreds of millions of TZD compounds." [4] *Takeda, 417 F. Supp. 2d at 378*. The patent specifically identified fifty-four compounds, including compound b, that were synthesized according to the procedures described in the patent, but did not disclose experimental data or test results for any of those compounds. The prosecution history, however, disclosed test results for nine specific compounds, including compound b. That information was provided to the examiner in response to a rejection in **[**16]** order to show that the claimed compounds of the *'200 patent* were superior to the known compounds that were disclosed in a cited reference. The court, however, found nothing in the *'200 patent*, or in its file history, to suggest to one of ordinary skill in the art that those nine compounds, out of the hundreds of millions of compounds covered by the patent application, were the best performing compounds as antidiabetics, and hence targets for modification to seek improved properties. *Id. at 375*.

4 Three divisional applications derive from the *'200 patent*. Those applications matured into *U.S. Patent 4,340,605*, *U.S. Patent 4,438,141*, and *U.S. Patent No. 4,444,779* (the "*'779 Patent*"). The *'779 patent* is of particular relevance in this appeal and is discussed below. *Takeda, 417 F. Supp. 2d at 378*.

**[*1358]** The court next considered an article that was published the following year in 1982 by T. Sodha et al. entitled "Studies on Antidiabetic Agents. II. Synthesis of 5-[4-(1-Methylcyclohexylmethoxy)-benzyl]thiazolidine-2,4-dione (ADD-3878) and Its Derivatives" ("Sodha II"). The Sodha II reference disclosed data relating to hypoglycemic activity and plasma triglyceride lowering activity for 101 TZD compounds. **[**17]** Those compounds did not include pioglitazone, but included compound b. Significantly, Sodha II identified three specific compounds that were deemed most favorable in terms of toxicity and activity. Notably, compound b was not identified as one of the three most favorable compounds. On the contrary, compound b, was singled out as causing "considerable increases in body weight and brown fat weight."

The court also considered Takeda's *'779 patent*. That patent covers a subset of compounds originally included in the *'200 patent* application, namely, TZD compounds "where the pyridyl or thiazolyl groups may be substituted." *Id. at 353*. The broadest claim of the *'779*

*patent* covers over one million compounds. *Id. at 378*. Compound b was specifically claimed in claim 4 of the patent. The court noted that a preliminary amendment in the prosecution history of the patent contained a statement that "the compounds in which these heterocyclic rings are substituted have become important, especially [compound b]." *Id.*

Based on the prior art as a whole, however, the court found that a person of ordinary skill in the art would not have selected compound b as a lead compound for antidiabetic treatment. Although **[**18]** the prosecution history of the *'779 patent* included the statement that characterized compound b as "especially important," the court found that any suggestion to select compound b was essentially negated by the disclosure of the Sodha II reference. The court reasoned that one of ordinary skill in the art would not have chosen compound b, notwithstanding the statement in the *'779 patent* prosecution history, "given the more exhaustive and reliable scientific analysis presented by Sodha II, which taught away from compound b, and the evidence from all of the TZD patents that Takeda filed contemporaneously with the '779 [p]atent showing that there were many promising, broad avenues for further research." *Id. at 380*.

The court found that the three compounds that the Sodha II reference identified as "most favorable" and "valuable for the treatment of maturity-onset diabetes," not compound b, would have served as the best "starting point for further investigation" to a person of ordinary skill in the art. *Id. at 376*. Because diabetes is a chronic disease and thus would require long term treatment, the court reasoned that researchers would have been dissuaded from selecting a lead compound that **[**19]** exhibited negative effects, such as toxicity, or other adverse side effects, especially one that causes "considerable increases in body weight and brown fat weight." *Id. at 376-77*. Thus, the court determined that the prior art did not suggest to one of ordinary skill in the art that compound b would be the best candidate as the lead compound for antidiabetic research.

Admissions from Alphapharm witnesses further buttressed the court's conclusion. Dr. Rosenberg, head of Alphapharm's intellectual property department, testified as a 30(b)(6) witness on behalf of Alphapharm. In discussing Sodha II, Dr. Rosenberg admitted that there was nothing in **[*1359]** the article that would recommend that a person of ordinary skill in the art choose compound b over other compounds in the article that had the same efficacy rating. Dr. Rosenberg, acknowledging that compound b had the negative side effects of increased body weight and brown fat, also admitted that a compound with such side effects would "presumably not" be a suitable candidate compound for treatment of Type II diabetes. Alphapharm's expert, Dr. Mosberg, concurred in that view at his deposition when he admitted that a medicinal chemist would find **[**20]** such side effects "undesirable."

Moreover, another Alphapharm 30(b)(6) witness, Barry Spencer, testified at his deposition that in reviewing the prior art, one of ordinary skill in the art would have chosen three compounds in Sodha II as lead compounds for research, not solely compound b. In addition, Takeda's witness, Dr. Morton, testified that at the time Sodha II was published, it was known that obesity contributed to insulin resistance and Type 2 diabetes. Thus, one of ordinary skill in the art would have concluded that Sodha II taught away from pyridyl compounds because it associated adverse side effects with compound b.

We do not accept Alphapharm's assertion that *KSR*, as well as another case recently decided by this court, *Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007)*, mandates reversal. Relying on *KSR*, Alphapharm argues that the claimed compounds would have been obvious because the prior art compound fell within "the objective reach of the claim," and the evidence demonstrated that using the techniques of homologation and ring-walking would have been "obvious to try." Additionally, Alphapharm argues that our holding in *Pfizer*, where we found obvious certain claims **[**21]** covering a particular acid-addition salt, directly supports its position.

We disagree. The *KSR* Court recognized that "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR, 127 S. Ct. at 1732*. In such circumstances, "the fact that a combination was obvious to try might show that it was obvious under *§ 103*." *Id.* That is not the case here. Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a broad selection of compounds any one of which could

have been selected as a lead compound for further investigation. Significantly, the closest prior art compound (compound b, the 6-methyl) exhibited negative properties that would have directed one of ordinary skill in the art away from that compound. Thus, this case fails to present the type of situation contemplated by the Court when it stated that an invention may be deemed obvious if it was "obvious to try." The evidence showed that it was not obvious to try.

Similarly, Alphapharm's reliance on *Pfizer* fares no better. [**22] In *Pfizer*, we held that certain claims covering the besylate salt of amlodipine would have been obvious. The prior art included a reference, referred to as the Berge reference, that disclosed a genus of pharmaceutically acceptable anions that could be used to form pharmaceutically acceptable acid addition salts, as well as other publications that disclosed the chemical characteristics of the besylate salt. *Pfizer, 480 F.3d at 1363*. Noting that our conclusion was based on the "particularized facts of this case," we found that the prior art provided [*1360] "ample motivation to narrow the genus of 53 pharmaceutically-acceptable anions disclosed by Berge to a few, including benzene sulphonate." *Id. at 1363, 1367*. Here, the court found nothing in the prior art to narrow the possibilities of a lead compound to compound b. In contrast, the court found that one of ordinary skill in the art would have chosen one of the many compounds disclosed in Sodha II, of which there were over ninety, that "did not disclose the existence of toxicity or side effects, and to engage in research to increase the efficacy and confirm the absence of toxicity of those compounds, rather than to choose as a starting point [**23] a compound with identified adverse effects." Thus, *Pfizer* does not control this case.

Based on the record before us, we conclude that the district court's fact-findings were not clearly erroneous and were supported by evidence in the record. Moreover, we reject the assertion that the court failed to correctly apply the law relating to prima facie obviousness of chemical compounds. Because Alphapharm's obviousness argument rested entirely on the court making a preliminary finding that the prior art would have led to the selection of compound b as the lead compound, and Alphapharm failed to prove that assertion, the court did not commit reversible error by failing to apply a presumption of motivation. We thus conclude that the court did not err in holding that Alphapharm failed to establish a prima facie case of obviousness. *See Eli Lilly & Co. v. Zenith Goldline Pharms., 471 F.3d 1369 (Fed. Cir. 2006)* (affirming the district court's finding of nonobviousness upon concluding, in part, that the prior art compound would not have been chosen as a lead compound).

*b. Choice of the Claimed Compounds*

Even if Alphapharm had established that preliminary finding, and we have concluded that it did [**24] not, the record demonstrates that Alphapharm's obviousness argument fails on a second ground. The district court found nothing in the prior art to suggest making the specific molecular modifications to compound b that are necessary to achieve the claimed compounds. In reaching that conclusion, the court first found that the process of modifying lead compounds was not routine at the time of the invention. *Takeda, 417 F. Supp. 2d at 380*. Dr. Mosberg opined that the steps of homologation and ring-walking were "routine steps in the drug optimization process," but the court found that testimony unavailing in light of the contrary, more credible, testimony offered by Takeda's experts. *Id. at 381*. In addition, the court relied on Dr. Rosenberg's admission that a person of ordinary skill in the art would "look at a host of substituents, such as chlorides, halides and others, not just methyls" in modifying the pyridyl ring. *Id.*

Pioglitazone differs from compound b in two respects, and one would have to both homologate the methyl group of compound b and move the resulting ethyl group to the 5-position on the pyridyl ring in order to obtain pioglitazone. With regard to homologation, the court [**25] found nothing in the prior art to provide a reasonable expectation that adding a methyl group to compound b would reduce or eliminate its toxicity. Based on the test results of the numerous compounds disclosed in Sodha II, the court concluded that "homologation had no tendency to decrease unwanted side effects" and thus researchers would have been inclined "to focus research efforts elsewhere." *Id. at 383*. Indeed, several other compounds exhibited similar or better potency than compound b, and one compound in particular, compound 99, that had no identified problems differed significantly [*1361] from compound b in structure. *Id. at 376 n.51*. Moreover, Dr. Mosberg agreed with Takeda's expert, Dr. Danishefsky, that the biological activities of various substituents were "unpredictable" based on the disclosure of Sodha II. *Id. at 384-85*. The court also found nothing in the *'200* and *'779 patents* to suggest to one of ordinary

skill in the art that homologation would bring about a reasonable expectation of success.

As for ring-walking, the court found that there was no reasonable expectation in the art that changing the positions of a substituent on a pyridyl ring would result in beneficial changes. [**26] Dr. Mosberg opined that the process of ring-walking was "known" to Takeda, but the court found that testimony inapt as it failed to support a reasonable expectation to one of ordinary skill in the art that performing that chemical change would cause a compound to be more efficacious or less toxic. *Id. at 382*. Moreover, Dr. Mosberg relied on the efficacy data of phenyl compounds in Sodha II, but the court found those data insufficient to show that the same effects would occur in pyridyl compounds.

Alphapharm relies on *In re Wilder, 563 F.2d 457 (CCPA 1977)*, for the proposition that differences in a chemical compound's properties, resulting from a small change made to the molecule, are reasonably expected to vary by degree and thus are insufficient to rebut a prima facie case of obviousness. In *Wilder*, our predecessor court affirmed the Board's holding that a claimed compound, which was discovered to be useful as a rubber antidegradant and was also shown to be nontoxic to human skin, would have been obvious in light of its homolog and isomer that were disclosed in the prior art. The evidence showed that the homolog was similarly nontoxic to the human skin, whereas the isomer was toxic. [**27] The court held that "one who claims a compound, per se, which is structurally similar to a prior art compound must rebut the presumed expectation that the structurally similar compounds have similar properties." *Id. at 460*. While recognizing that the difference between the isomer's toxicity and the nontoxicity of the homolog and claimed compound "indicate[d] some degree of unpredictability," the court found that the appellant failed to "point out a single actual difference in properties between the claimed compound and the homologue," and thus failed to rebut the presumption. *Wilder, 563 F.2d at 460*.

We would note that since our *Wilder* decision, we have cautioned "that generalization should be avoided insofar as specific chemical structures are alleged to be prima facie obvious one from the other," *Grabiak, 769 F.2d at 731*. In addition to this caution, the facts of the present case differ significantly from the facts of *Wilder*. Here, the court found that pioglitazone exhibited unexpectedly superior properties over the prior art compound b. *Takeda, 417 F. Supp. 2d at 385*. The court considered a report entitled "Preliminary Studies on Toxicological Effects of Ciglitazone-Related Compounds [**28] in the Rats" that was presented in February 1984 by Dr. Takeshi Fujita, then-Chief Scientist of Takeda's Biology Research Lab and co-inventor of the *'777 patent*. That report contained results of preliminary toxicity studies that involved selected compounds, including pioglitazone and compound b. Compound b was shown to be "toxic to the liver, heart and erythrocytes, among other things," whereas pioglitazone was "comparatively potent" and "showed no statistically significant toxicity." *Id. at 356-57*. During the following months, Takeda performed [*1362] additional toxicity studies on fifty compounds that had been already synthesized and researched by Takeda, including pioglitazone. The compounds were tested for potency and toxicity. The results were presented in another report by Fujita entitled "Pharmacological and Toxicological Studies of Ciglitazone and Its Analogues." Pioglitazone was shown to be the only compound that exhibited no toxicity, although many of the other compounds were found to be more potent. *Id. at 358*.

Thus, the court found that there was no reasonable expectation that pioglitazone would possess the desirable property of nontoxicity, particularly in light of the toxicity [**29] of compound b. The court's characterization of pioglitazone's unexpected results is not clearly erroneous. As such, *Wilder* does not aid Alphapharm because, unlike the homolog and claimed compound in *Wilder* that shared similar properties, pioglitazone was shown to differ significantly from compound b, of which it was not a homolog, in terms of toxicity. Consequently, Takeda rebutted any presumed expectation that compound b and pioglitazone would share similar properties.

Alphapharm also points to a statement Takeda made during the prosecution of the *'779 patent* as evidence that there was a reasonable expectation that making changes to the pyridyl region of compound b would lead to "better toxicity than the prior art." During prosecution of the *'779 patent*, in response to an enablement rejection, Takeda stated that "there should be no reason in the instant case for the Examiner to doubt that the claimed compounds having the specified substituent would function as a hypolipidemic and hypoglycemic agent as specified in the instant disclosure." That statement, however,

indicates only that changes to the left moiety of a lead compound would create compounds with the same properties as the [**30] compounds of the prior art; it does not represent that lower toxicity would result. And even if the statement did so represent, it does not refer to any specific substituent at any specific position of TZD's left moiety as particularly promising. As the court correctly noted, the compounds disclosed in the '779 *patent* included a variety of substituents, including lower alkyls, halogens, and hydroxyl groups, attached to a pyridyl or thiazolyl group. As discussed *supra*, the district court found that the claims encompassed over one million compounds. Thus, we disagree with Alphapharm that that statement provided a reasonable expectation to one of ordinary skill in the art that performing the specific steps of replacing the methyl group of the 6-methyl compound with an ethyl group, and moving that substituent to the 5-position of the ring, would have provided a broad safety margin, particularly in light of the district court's substantiated findings to the contrary.

We thus conclude that Alphapharm's challenges fail to identify grounds for reversible error. The court properly considered the teachings of the prior art and made credibility determinations regarding the witnesses at trial. [**31] We do not see any error in the district court's determination that one of ordinary skill in the art would not have been prompted to modify compound b, using the steps of homologation and ring-walking, to synthesize the claimed compounds. Because the court's conclusions are not clearly erroneous and are supported by the record evidence, we find no basis to disturb them.

The court properly concluded that Alphapharm did not make out a prima facie case of obviousness because Alphapharm [*1363] failed to adduce evidence that compound b would have been selected as the lead compound and, even if that preliminary showing had been made, it failed to show that there existed a reason, based on what was known at the time of the invention, to perform the chemical modifications necessary to achieve the claimed compounds.

In light of our conclusion that Alphapharm failed to prove that the claimed compounds would have been prima facie obvious, we need not consider any objective indicia of nonobviousness. [5]

> 5 The concurrence, while agreeing that the question of the "overbreadth" of claims 1 and 5 has been waived, states further that the 6-ethyl compound, which is within the scope of claims 1 and 5, has not been [**32] shown to possess unexpected results sufficient to overcome a prima facie case of obviousness, and hence claims 1 and 5 are likely invalid as obvious. Since waiver is sufficient to answer the point being raised, no further comment need be made concerning its substance.

*2. Scope and Content of the Prior Art*

Alphapharm also assigns error to the district court's determination regarding the scope and content of the prior art. Alphapharm asserts that the court excluded the prosecution history of the '779 *patent* from the scope of the prior art after wrongly concluding that it was not accessible to the public. Takeda responds that the court clearly considered the '779 *patent* prosecution history, which was admitted into evidence on the first day of testimony. Takeda urges that the court's consideration of the prosecution history is apparent based on its extensive analysis of the '779 *patent* and the file history that appears in the court's opinion.

We agree with Takeda that the district court did not err in its consideration of the scope of the prior art. As discussed above, the court considered the prosecution history, and even expressly considered one of the key statements in the prosecution [**33] history upon which Alphapharm relies in support of its position that compound b would have been chosen as the lead compound. *Takeda, 417 F. Supp. 2d at 378*. In considering the prosecution history of the '779 *patent*, the court noted that Takeda filed a preliminary amendment on March 15, 1983, in which its prosecuting attorney stated that "the compounds in which these heterocyclic rings are substituted have become important, especially [the 6-methyl compound]." *Id.* The court rejected Alphapharm's assertion that that statement supported the conclusion that compound b would have been selected as a lead compound. Rather, the court found that viewing the prior art as a whole, the prior art showed "that Takeda was actively conducting research in many directions, and had not narrowed its focus to compound b." *Id. at 379*. Thus, while the district court may have incorrectly implied that prosecution histories are not accessible to the public, *see id.* at n.59, *see also Custom Accessories, Inc. v. Jeffrey-Allan Indus., 807 F.2d 955 (Fed. Cir. 1986)* ("[t]he person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior

art"), the court nonetheless considered **[**34]** the prosecution history of the *'779 patent* in its obviousness analysis and accorded proper weight to the statements contained therein. Thus, any error committed by the court in this regard was harmless error.

We have considered Alphapharm's remaining arguments and find none that warrant reversal of the district court's decision.

**[*1364]** CONCLUSION

We affirm the district court's determination that claims 1, 2, and 5 of the *'777 patent* have not been shown to have been obvious and hence invalid.

*AFFIRMED*

**CONCUR BY:** DYK

**CONCUR**

DYK, *Circuit Judge*, concurring.

I join the opinion of the court insofar as it upholds the district court judgment based on a determination that a claim to pioglitazone (the 5-ethyl compound) would be non-obvious over the prior art. The problem is that only one of the three claims involved here--claim 2--is limited to pioglitazone. In my view, the breadth of the other two claims, claims 1 and 5 of *U.S. Patent No. 4,867,777 ("'777 patent")*--which are also referenced in the judgment--renders them likely invalid.

All of the compounds claimed in claims 1, 2 and 5 were included in generic claims in the prior art *U.S. Patent No. 4,287,200 ("'200 patent")*. Unfortunately our law concerning when a species **[**35]** is patentable over a genus claimed in the prior art is less than clear. It is, of course, well established that a claim to a genus does not necessarily render invalid a later claim to a species within that genus. *See Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash., 334 F.3d 1264, 1270 (Fed. Cir. 2003)*. In my view a species should be patentable over a genus claimed in the prior art only if unexpected results have been established. Our case law recognizes the vital importance of a finding of unexpected results, both in this context and in the closely related context where a prior art patent discloses a numerical range and the patentee seeks to claim a subset of that range. *See Application of Petering, 301 F.2d 676, 683, 49 C.C.P.A. 993, 1962 Dec. Comm'r Pat. 232 (C.C.P.A. 1962)* (species found patentable when genus claimed in prior art because unexpected properties of the species were shown); *see also Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1371 (Fed. Cir. 2007)* (relying on lack of unexpected results in determining that species claim was obvious in view of prior art genus claim); *In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990)* (when applicant claims a subset of a range disclosed in a prior art patent, the applicant **[**36]** must generally show that "the claimed range achieves unexpected results relative to the prior art range.").

While the 5-ethyl compound (pioglitazone) is within the scope of the *'200 patent*, there is clear evidence, as the majority correctly finds, of unexpected results regarding that compound, and therefore its validity is not in question on this ground. However, at oral argument the patentee admitted that the prior art *'200 patent* also generically covers the 6-ethyl compound, which is within the scope of claims 1 and 5 of the *'777 patent*, and admitted that there is no evidence of unexpected results for the 6-ethyl compound. Under such circumstances, I believe that the 6-ethyl is likely obvious, and consequently claims 1 and 5 are likely invalid for obviousness. However, the argument as to the overbreadth of claims 1 and 5 has been waived, because it was not raised in the opening brief. In any event, as a practical matter, the judgment finding that the appellants' filing of the ANDA for pioglitazone is an infringement and barring the making of pioglitazone is supported by the finding that claim 2 standing alone is not invalid and is infringed.

LEXSEE

**IN RE THOMAS F. DEUEL, YUE-SHENG LI, NED R. SIEGEL and PETER G. MILNER**

**94-1202**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***51 F.3d 1552*; *1995 U.S. App. LEXIS 6200*; *34 U.S.P.Q.2D (BNA) 1210***

**March 28, 1995, Decided**

**PRIOR HISTORY:** **[**1]** Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences. (Serial No. 07/542,232).

**DISPOSITION:** REVERSED

**COUNSEL:** G. Harley Blosser, Senniger, Powers, Leavitt & Roedel, of St. Louis, Missouri, argued for appellants. With him on the brief was Donald G. Leavitt.

Donald S. Chisum, Morrison & Foerster, of Seattle, Washington, argued for Amicus Curiae, The Biotechnology Industry Association and The Bay Area Bioscience Center. With him on the brief were Debra A. Shetka, Morrison & Forester, of Palo Alto, California and Robert P. Blackburn, of Emeryville, California.

Teddy S. Gron, Acting Associate Solicitor, of Arlington, Virginia, argued for appellee. With him on the brief was Albin F. Drost, Acting Solicitor. Nancy J. Linck, Office of the Solicitor, of Arlington, Virginia, represented appellee.

**JUDGES:** Before ARCHER, Chief Judge, NIES and LOURIE, Circuit Judges.

**OPINION BY:** LOURIE

**OPINION**

**[*1553]** LOURIE, *Circuit Judge*.

Thomas F. Deuel, Yue-Sheng Li, Ned R. Siegel, and Peter G. Milner (collectively "Deuel") appeal from the November 30, 1993 decision of the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences affirming the examiner's final rejection of **[**2]** claims 4-7 of application Serial No. 07/542,232, entitled "Heparin-Binding **[*1554]** Growth Factor," as unpatentable on the ground of obviousness under *35 U.S.C. § 103 (1988)*. *Ex parte Deuel, 33 USPQ2d 1445 (Bd. Pat. App. Int. 1993)*. Because the Board erred in concluding that Deuel's claims 5 and 7 directed to specific cDNA molecules would have been obvious in light of the applied references, and no other basis exists in the record to support the rejection with respect to claims 4 and 6 generically covering all possible DNA molecules coding for the disclosed proteins, we reverse.

BACKGROUND

The claimed invention relates to isolated and purified DNA and cDNA molecules encoding heparin-binding growth factors ("HBGFs"). [1] HBGFs are proteins that stimulate mitogenic activity (cell division) and thus facilitate the repair or replacement of damaged or diseased tissue. DNA (deoxyribonucleic acid) is a generic term which encompasses an enormous number of complex macromolecules made up of nucleotide units. DNAs consist of four different nucleotides containing the nitrogenous bases adenine, guanine, cytosine, and thymine. A sequential grouping of three such nucleotides (a "codon") codes for **[**3]** one amino acid. A DNA's sequence of codons thus determines the sequence of amino acids assembled during protein synthesis. Since

there are 64 possible codons, but only 20 natural amino acids, most amino acids are coded for by more than one codon. This is referred to as the "redundancy" or "degeneracy" of the genetic code.

1 For a more extensive discussion of recombinant DNA technology, *see In re O'Farrell, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir. 1988)*; *Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016* (Fed. Cir.), *cert. denied, 502 U.S. 856 (1991)*.

DNA functions as a blueprint of an organism's genetic information. It is the major component of genes, which are located on chromosomes in the cell nucleus. Only a small part of chromosomal DNA encodes functional proteins.

Messenger ribonucleic acid ("mRNA") is a similar molecule that is made or transcribed from DNA as part of the process of protein synthesis. Complementary DNA ("cDNA") is a complementary copy ("clone") [**4] of mRNA, made in the laboratory by reverse transcription of mRNA. Like mRNA, cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids. The reverse is not true, however, due to the degeneracy of the code. Many other DNAs may code for a particular protein. The functional relationships between DNA, mRNA, cDNA, and a protein may conveniently be expressed as follows:

| | | |
|---|---|---|
| genomic | | |
| DNA | mRNA | protein |
| | cDNA | other DNAs |

Collections ("libraries") of DNA and cDNA molecules derived from various species may be constructed in the laboratory or obtained from commercial sources. Complementary DNA libraries contain a mixture of cDNA clones reverse-transcribed from the mRNAs found in a specific tissue source. Complementary DNA libraries are tissue-specific because proteins and their corresponding mRNAs are only made ("expressed") in specific tissues, depending upon the protein. Genomic DNA ("gDNA") libraries, by contrast, theoretically contain all of a species' chromosomal DNA. The molecules present in cDNA and DNA libraries may be [**5] of unknown function and chemical structure, and [*1555] the proteins which they encode may be unknown. However, one may attempt to retrieve molecules of interest from cDNA or gDNA libraries by screening such libraries with a gene probe, which is a synthetic radiolabelled nucleic acid sequence designed to bond ("hybridize") with a target complementary base sequence. Such "gene cloning" techniques thus exploit the fact that the bases in DNA always hybridize in complementary pairs: adenine bonds with thymine and guanine bonds with cytosine. A gene probe for potentially isolating DNA or cDNA encoding a protein may be designed once the protein's amino acid sequence, or a portion thereof, is known.

As disclosed in Deuel's patent application, Deuel isolated and purified HBGF from bovine uterine tissue, found that it exhibited mitogenic activity, and determined the first 25 amino acids of the protein's N-terminal sequence. [2] Deuel then isolated a cDNA molecule encoding bovine uterine HBGF by screening a bovine uterine cDNA library with an oligonucleotide probe designed using the experimentally determined N-terminal sequence of the HBGF. Deuel purified and sequenced the cDNA molecule, which was [**6] found to consist of a sequence of 1196 nucleotide base pairs. From the cDNA's nucleotide sequence, Deuel then predicted the complete amino acid sequence of bovine uterine HBGF disclosed in Deuel's application.

2 Deuel determined that the N-terminal sequence of bovine uterus HBGF is Gly-Lys-Lys-Glu-Lys-Pro-Glu-Lys-Lys-Val-Lys-Lys-Ser-Asp-Cy

Deuel also isolated a cDNA molecule encoding

human placental HBGF[2] by screening a human placental cDNA library using the isolated bovine uterine cDNA clone as a probe. Deuel purified and sequenced the human placental cDNA clone, which was found to consist of a sequence of 961 nucleotide base pairs. From the nucleotide sequence of the cDNA molecule encoding human placental HBGF, Deuel predicted the complete amino acid sequence of human placental HBGF disclosed in Deuel's application. The predicted human placental and bovine uterine HBGFs each have 168 amino acids and calculated molecular weights of 18.9 kD. Of the 168 amino acids present **[**7]** in the two HBGFs discovered by Deuel, 163 are identical. Deuel's application does not describe the chemical structure of, or state how to isolate and purify, any DNA or cDNA molecule except the disclosed human placental and bovine uterine cDNAs, which are the subject of claims 5 and 7.

Claims 4-7 on appeal are all independent claims and read, in relevant part, as follows:

4. A purified and isolated DNA sequence consisting of a sequence encoding human heparin binding growth factor of 168 amino acids having the following amino acid sequence:

Met Gln Ala . . . [remainder of 168 amino acid sequence].

5. The purified and isolated cDNA of human heparin-binding growth factor having the following nucleotide sequence:

GTCAAAGGCA . . . [remainder of 961 nucleotide sequence].

6. A purified and isolated DNA sequence consisting of a sequence encoding bovine heparin binding growth factor of 168 amino acids having the following amino acid sequence:

Met Gln Thr . . . [remainder of 168 amino acid sequence].

7. The purified and isolated cDNA of bovine heparin-

binding growth factor having the following nucleotide sequence:

GAGTGGAGAG . . . [remainder of 1196 nucleotide **[**8]** sequence].

Claims 4 and 6 generically encompass *all* isolated/purified DNA sequences (natural and synthetic) encoding human and bovine HBGFs, despite the fact that Deuel's application does not describe the chemical structure of, or tell how to obtain, any DNA or cDNA except the two disclosed cDNA molecules. Because of the redundancy of the genetic code, claims 4 and 6 each encompass an enormous number of DNA molecules, including the isolated/purified chromosomal DNAs encoding the human and bovine proteins. Claims 5 and 7, on the other hand, are directed to the specifically disclosed cDNA molecules encoding human and bovine HBGFs, respectively.

During prosecution, the examiner rejected claims 4-7 under *35 U.S.C. § 103* as unpatentable over the combined teachings of Bohlen [3] **[*1556]** and Maniatis. [4] The Bohlen reference discloses a group of protein growth factors designated as heparin-binding brain mitogens ("HBBMs") useful in treating burns and promoting the formation, maintenance, and repair of tissue, particularly neural tissue. Bohlen isolated three such HBBMs from human and bovine brain tissue. These proteins have respective molecular weights of 15 kD, 16 kD, and 18 kD. Bohlen determined **[**9]** the first 19 amino acids of the proteins' N-terminal sequences, which were found to be identical for human and bovine HBBMs. [5] Bohlen teaches that HBBMs are brain-specific, and suggests that the proteins may be homologous between species. The reference provides no teachings concerning DNA or cDNA coding for HBBMs.

3 European Patent Application No. 0326075, naming Peter Bohlen as inventor, published August 2, 1989.

4 Maniatis et al., *Molecular Cloning: A Laboratory Manual*, "Screening Bacteriophage [lambda] Libraries for Specific DNA Sequences by Recombination in *Escherichia coli*," Cold Spring Harbor Laboratory, New York, 1982, pp. 353-361.

5 Bohlen's disclosed N-terminal sequence for human and bovine HBBMs is Gly-Lys-Lys-Glu-Lys-Pro-Glu-Lys-Lys-Val-Lys-Lys-Ser-Asp-Cy This sequence matches the first 19 amino acids of Deuel's disclosed N-terminal sequence.

Maniatis describes a method of isolating DNAs or cDNAs by screening a DNA or cDNA library with a gene

probe. The reference [**10] outlines a general technique for cloning a gene; it does not describe how to isolate a particular DNA or cDNA molecule. Maniatis does not discuss certain steps necessary to isolate a target cDNA, *e.g.*, selecting a tissue-specific cDNA library containing a target cDNA and designing an oligonucleotide probe that will hybridize with the target cDNA.

The examiner asserted that, given Bohlen's disclosure of a heparin-binding protein and its N-terminal sequence and Maniatis's gene cloning method, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to clone a gene for HBGF. [6] According to the examiner, Bohlen's published N-terminal sequence would have motivated a person of ordinary skill in the art to clone such a gene because cloning the gene would allow recombinant production of HBGF, a useful protein. The examiner reasoned that a person of ordinary skill in the art could have designed a gene probe based on Bohlen's disclosed N-terminal sequence, then screened a DNA library in accordance with Maniatis's gene cloning method to isolate a gene encoding an HBGF. The examiner did not distinguish between claims 4 and 6 generically [**11] directed to all DNA sequences encoding human and bovine HBGFs and claims 5 and 7 reciting particular cDNAs.

> 6 The examiner and the Board apparently used the term "gene" to refer both to natural (chromosomal) DNA and synthetic cDNA. We will use the several terms as appropriate.

In reply, Deuel argued, *inter alia*, that Bohlen teaches away from the claimed cDNA molecules because Bohlen suggests that HBBMs are brain-specific and, thus, a person of ordinary skill in the art would not have tried to isolate corresponding cDNA clones from human placental and bovine uterine cDNA libraries. The examiner made the rejection final, however, asserting that

> the starting materials are not relevant in this case, because it was well known in the art at the time the invention was made that proteins, especially the general class of heparin binding proteins, are highly homologous between species and tissue type. It would have been entirely obvious to attempt to isolate a known protein from different tissue types and [**12] even different species.

No prior art was cited to support the proposition that it would have been obvious to screen human placental and bovine uterine cDNA libraries for the claimed cDNA clones. Presumably, the examiner was relying on Bohlen's suggestion that HBBMs may be homologous between species, although the examiner did not explain how homology between species suggests homology between tissue types.

The Board affirmed the examiner's final rejection. In its opening remarks, the Board noted that it is "constantly advised by the [*1557] patent examiners, who are highly skilled in this art, that cloning procedures are routine in the art." According to the Board, "the examiners urge that when the sequence of a protein is placed into the public domain, the gene is also placed into the public domain because of the routine nature of cloning techniques." Addressing the rejection at issue, the Board determined that Bohlen's disclosure of the existence and isolation of HBBM, a functional protein, would also advise a person of ordinary skill in the art that a gene exists encoding HBBM. The Board found that a person of ordinary skill in the art would have been motivated to isolate such [**13] a gene because the protein has useful mitogenic properties, and isolating the gene for HBBM would permit large quantities of the protein to be produced for study and possible commercial use. Like the examiner, the Board asserted, without explanation, that HBBMs are the same as HBGFs and that the genes encoding these proteins are identical. The Board concluded that "the Bohlen reference would have suggested to those of ordinary skill in this art that they should make the gene, and the Maniatis reference would have taught a technique for 'making' the gene with a reasonable expectation of success." Responding to Deuel's argument that the claimed cDNA clones were isolated from human placental and bovine uterine cDNA libraries, whereas the combined teachings of Bohlen and Maniatis would only have suggested screening a brain tissue cDNA library, the Board stated that "the claims before us are directed to the product and not the method of isolation. Appellants have not shown that the claimed DNA was not present in and could not have been readily isolated from the brain tissue utilized by Bohlen." Deuel now appeals. [7]

> 7 Deuel is supported in its appeal by an *amicus curiae* brief submitted by the Biotechnology Industry Organization and the Bay Area Science

Center. Amici urge that, contrary to controlling precedent, the PTO has unlawfully adopted a *per se* rule that a gene is *prima facie* obvious when at least part of the amino acid sequence of the protein encoded by the gene is known in the prior art.

[**14] DISCUSSION

Obviousness is a question of law, which we review *de novo*, though factual findings underlying the Board's obviousness determination are reviewed for clear error. *In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991)*; *In re Woodruff, 919 F.2d 1575, 1577, 16 USPQ2d 1934, 1935 (Fed. Cir. 1990)*. The examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993)*; *In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992)*. Only if this burden is met does the burden of coming forward with rebuttal argument or evidence shift to the applicant. *Rijckaert, 9 F.3d at 1532, 28 USPQ2d at 1956*. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988)*.

On appeal, Deuel challenges the Board's determination that the applied references establish a *prima facie* case of obviousness. In response, the PTO maintains that the claimed invention would have been *prima facie* obvious [**15] over the combined teachings of Bohlen and Maniatis. Thus, the appeal raises the important question whether the combination of a prior art reference teaching a method of gene cloning, together with a reference disclosing a partial amino acid sequence of a protein, may render DNA and cDNA molecules encoding the protein *prima facie* obvious under *§ 103*.

Deuel argues that the PTO failed to follow the proper legal standard in determining that the claimed cDNA molecules would have been *prima facie* obvious despite the lack of structurally similar compounds in the prior art. Deuel argues that the PTO has not cited a reference teaching cDNA molecules, but instead has improperly rejected the claims based on the alleged obviousness of a method of making the molecules. We agree.

Because Deuel claims new chemical entities in structural terms, a *prima facie* case of unpatentability requires that the teachings of the prior art suggest *the claimed compounds* to a person of ordinary skill in the art. [*1558] Normally a *prima facie* case of obviousness is based upon structural similarity, *i.e.*, an established structural relationship between a prior art compound and the claimed compound. [**16] Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties. Similarly, a known compound may suggest its analogs or isomers, either geometric isomers (cis v. trans) or position isomers (*e.g.*, ortho v. para).

In all of these cases, however, the prior art teaches a specific, structurally-definable compound and the question becomes whether the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention. *See In re Jones, 958 F.2d 347, 351, 21 USPQ2d 1941, 1944 (Fed. Cir. 1992)*; *In re Dillon, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990)* (en banc) ("structural similarity between claimed and prior art subject matter, . . . where the prior art gives reason or motivation to make the claimed compositions, creates a *prima facie* case of obviousness"), *cert. denied, 500 U.S. 904, 114 L. Ed. 2d 77, 111 S. Ct. 1682 (1991)*; *In re Grabiak* [**17] , *769 F.2d 729, 731-32, 226 USPQ 870, 872 (Fed. Cir. 1985)* ("In the case before us there must be adequate support in the prior art for the [prior art] ester/[claimed] thioester change in structure, in order to complete the PTO's *prima facie* case and shift the burden of going forward to the applicant."); *In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984)* ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compound.").

Here, the prior art does not disclose any relevant cDNA molecules, let alone close relatives of the specific, structurally-defined cDNA molecules of claims 5 and 7 that might render them obvious. Maniatis suggests an allegedly obvious process for trying to isolate cDNA molecules, but that, as we will indicate below, does not fill the gap regarding the subject matter of claims 5 and 7. Further, while the general idea of the claimed molecules, their function, and their general chemical nature may

have been obvious from Bohlen's teachings, and the knowledge that some gene existed may have been clear, the precise cDNA molecules of claims 5 and **[**18]** 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules. The redundancy of the genetic code precluded contemplation of or focus on the specific cDNA molecules of claims 5 and 7. Thus, one could not have conceived the subject matter of claims 5 and 7 based on the teachings in the cited prior art because, until the claimed molecules were actually isolated and purified, it would have been highly unlikely for one of ordinary skill in the art to contemplate what was ultimately obtained. What cannot be contemplated or conceived cannot be obvious.

The PTO's theory that one might have been motivated to try to do what Deuel in fact accomplished amounts to speculation and an impermissible hindsight reconstruction of the claimed invention. It also ignores the fact that claims 5 and 7 are limited to specific compounds, and any motivation that existed was a general one, to try to obtain a gene that was yet undefined and may have constituted many forms. A general motivation to search for some gene that exists does not necessarily make obvious a specifically-defined gene that is subsequently obtained as a result **[**19]** of that search. More is needed and it is not found here.

The genetic code relationship between proteins and nucleic acids does not overcome the deficiencies of the cited references. A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be **[*1559]** prepared. We recently held in *In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994)*, that a broad genus does not necessarily render obvious each compound within its scope. Similarly, knowledge of a protein does not give one a conception of a particular DNA encoding it. Thus, *a fortiori*, Bohlen's disclosure of the N-terminal portion of a protein, which the PTO urges is the same as HBGF, would not have suggested the particular cDNA molecules defined by claims 5 and 7. This is so even though one skilled in the art knew that some DNA, albeit not in purified and isolated form, **[**20]** did exist. The compounds of claims 5 and 7 are specific compounds not suggested by the prior art. A different result might pertain, however, if there were prior art, *e.g.*, a protein of sufficiently small size and simplicity, so that lacking redundancy, each possible DNA would be obvious over the protein. *See In re Petering, 49 C.C.P.A. 993, 301 F.2d 676 (CCPA 1962)* (prior art reference disclosing limited genus of 20 compounds rendered every species within the genus unpatentable). That is not the case here.

The PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods. *See In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993)*. In *Bell*, the PTO asserted a rejection based upon the combination of a primary reference disclosing a protein (*and its complete amino acid sequence*) with a secondary reference describing a general method of gene cloning. We reversed the rejection, holding in part that "the PTO's focus on Bell's method is misplaced. Bell does not claim a method. Bell claims compositions, and the issue is the obviousness of the claimed compositions, not of the method **[**21]** by which they are made." *Id.*

We today reaffirm the principle, stated in Bell, that the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs. A prior art disclosure of a process *reciting a particular compound* or obvious variant thereof as a product of the process is, of course, another matter, raising issues of anticipation under *35 U.S.C. § 102* as well as obviousness under *§ 103*. Moreover, where there is prior art that suggests a claimed compound, the existence, or lack thereof, of an enabling process for making that compound is surely a factor in any patentability determination. *See In re Brown, 51 C.C.P.A. 1254, 329 F.2d 1006, 141 USPQ 245 (CCPA 1964)* (reversing rejection for lack of an enabling method of making the claimed compound). There must, however, still be prior art that suggests the claimed compound in order for a *prima facie* case of obviousness to be made out; as we have already indicated, that prior art was lacking here with respect to claims 5 and 7. Thus, even if, as the examiner **[**22]** stated, the existence of general cloning techniques, coupled with knowledge of a protein's structure, might have provided motivation to

prepare *a* cDNA or made it obvious to prepare *a* cDNA, that does not necessarily make obvious a particular claimed cDNA. "Obvious to try" has long been held not to constitute obviousness. *In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1680-81 (Fed. Cir. 1988).* A general incentive does not make obvious a particular result, nor does the existence of techniques by which those efforts can be carried out. Thus, Maniatis's teachings, even in combination with Bohlen, fail to suggest the claimed invention.

The PTO argues that a compound may be defined by its process of preparation and therefore that a conceived process for making or isolating it provides a definition for it and can render it obvious. It cites *Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016* (Fed. Cir.), *cert. denied, 502 U.S. 856 (1991)*, for that proposition. We disagree. The fact that one can conceive a general process in advance for preparing an *undefined* compound does not mean that a claimed *specific* compound was precisely envisioned **[**23]** and therefore obvious. A substance may indeed be defined by its process of preparation. That occurs, however, when it has already been prepared by that process and one therefore knows that the result of that process is the stated compound. The process is part of the definition of the compound. **[*1560]** But that is not possible in advance, especially when the hypothetical process is only a general one. Thus, a conceived method of preparing some undefined DNA does not define it with the precision necessary to render it obvious over the protein it encodes. We did not state otherwise in *Amgen. See Amgen, 927 F.2d at 1206-9, 18 USPQ2d at 1021-23* (isolated/purified human gene held nonobvious; no conception of gene without envisioning its precise identity despite conception of general process of preparation).

We conclude that, because the applied references do not teach or suggest the claimed cDNA molecules, the final rejection of claims 5 and 7 must be reversed. *See also Bell, 991 F.2d at 784-85, 26 USPQ2d at 1531-32* (human DNA sequences encoding IGF proteins nonobvious over asserted combination of references showing gene cloning method and complete amino acid sequences of IGFs).

Claims **[**24]** 4 and 6 are of a different scope than claims 5 and 7. As is conceded by Deuel, they generically encompass all DNA sequences encoding human and bovine HBGFs. Written in such a result-oriented form, claims 4 and 6 are thus tantamount to the general idea of all genes encoding the protein, all solutions to the problem. Such an idea might have been obvious from the *complete* amino acid sequence of the protein, coupled with knowledge of the genetic code, because this information may have enabled a person of ordinary skill in the art to envision the idea of, and, perhaps with the aid of a computer, even identify all members of the claimed genus. The Bohlen reference, however, only discloses a partial amino acid sequence, and thus it appears that, based on the above analysis, the claimed genus would not have been obvious over this prior art disclosure. We will therefore also reverse the final rejection of claims 4 and 6 because neither the Board nor the patent examiner articulated any separate reasons for holding these claims unpatentable apart from the grounds discussed above.

One further matter requires comment. Because Deuel's patent application does not describe how to obtain any DNA **[**25]** except the disclosed cDNA molecules, claims 4 and 6 may be considered to be inadequately supported by the disclosure of the application. *See generally Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28* (Fed. Cir.) (generic DNA sequence claims held invalid under *35 U.S.C. § 112*, first paragraph), *cert. denied, 502 U.S. 856 (1991)*; *In re Fisher, 57 C.C.P.A. 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)* (*Section 112* "requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). As this issue is not before us, however, we will not address whether claims 4 and 6 satisfy the enablement requirement of *§ 112*, first paragraph, but will leave to the PTO the question whether any further rejection is appropriate.

We have considered the PTO's remaining arguments and find them not persuasive.

CONCLUSION

The Board's decision affirming the final rejection of claims 4-7 is reversed.

*REVERSED*

LEXSEE 49 FR 3768

*49 FR 3768*

DEPARTMENT OF COMMERCE

Patent and Trademark Office

AGENCY: Patent and Trademark Office, Commerce.

37 CFR Part 1

Patent Interference Proceedings

[Docket No. 40104-03]

January 30, 1984

ACTION: Notice of proposed rulemaking.

SUMMARY: This Administration on July 18, 1983, forwarded to the Congress a legislative proposal to combine the Board of Appeals and the Board of Patent Interferences into a single Board of Appeals and Interferences. This legislation is now being considered in the House (H.R. 4462) and Senate (S. 1538, as amended and reported by the Subcommittee on Patents, Copyrights and Trademarks of the Senate Committee on the Judiciary). In order to afford the public the maximum time for studying and comment, this proposed notice of rulemaking sets forth changes that the Patent and Trademark Office (PTO) is proposing to the rules governing interferences should the legislation be enacted. The proposing of rule changes on the assumption that the legislation will be passed is not in any way intended to usurp the prerogatives of the Congress to act as it wishes in regard to the proposed legislation. Should the Congress amend the proposed legislation, this notice of proposed rulemaking will be revised to satisfy Congressional intent. Should Congress fail to enact the proposed legislation, this notice will likewise be revised to streamline interference proceedings without the merger of the two Boards. Interested persons are invited to comment on the proposed rules.

DATES: Comments must be submitted on or before May 7, 1984; a public hearing will be held on May 15, 1984, at 9:30 A.M.; requests to present oral testimony should be received on or before May 7, 1984.

ADDRESS: Address written comments and requests to present oral testimony to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, Attention: Fred E. McKelvey. The hearing will be held in the Commissioner's Conference Room, 11th Floor, Crystal Plaza Building 3, Room 11-C-10, 2021 Jefferson Davis Highway, Arlington, Virginia. Written comments and a transcript of the public hearing will be available for public inspection in Room 12B10, Crystal Gateway II, 1225 Jefferson Davis Highway, Arlington, Virginia.
FOR FURTHER INFORMATION CONTACT: Fred E. McKelvey by telephone at (703) 557-4025 (if no answer,

claim to invention E.

Example 27

In this example, the facts are the same as in Example 26 except that judgment is awarded on Counts 1 and 2 to senior party applicant AP. Junior party applicant AM would be estopped to obtain a patent containing claims to invention E, because applicant AM failed to move to add a count to invention E in the interference. Senior party applicant AP would not be estopped to obtain a patent containing claims to invention E.

Example 28

In this example, the facts are the same as in Example 26 except that judgment is awarded on Count 1 to junior party applicant AM and judgment is awarded on Count 2 to senior party applicant AP. Both parties would be estopped to obtain a patent containing claims to invention E, because neither moved to add a count to invention E during the interference.

Example 29

Applicant AQ discloses and claims invention "F." Applicant AR discloses and claims separate patentable inventions "F" and "G." The assignee of applicant AQ also owns an application AS which discloses and claims invention "G." An interference is declared between applicant AQ and applicant AR. The sole count is directed to invention F. No motion is filed by applicant AQ or its assignee to declare an additional interference between applicant AR and applicant AS with a count to invention G. A judgment as to the sole count is awarded to applicant AR. Applicant AS and the assignee would be estopped to obtain a patent containing claims to invention G, because applicant AR and the assignee failed to move to declare an additional interference with a count to invention G.

Example 30

The facts in this example are the same as the facts in Example 29 except that judgment as to the sole count is awarded to applicant AQ. Applicant AS and the assignee would not be estopped, because applicant AQ was awarded a judgment as to all counts.

Example 31

Applicant AT discloses a generic invention to "solvent" and a species to "benzene." Application AT contains a patentable claim 1 (solvent) and no other claims. Applicant AU discloses the generic invention to "solvent" and species to "benzene" and "toluene." Application AU contains patentable claim 3 (solvent) and no other claims. An interference is declared with a single count (solvent). Claim 1 of application AT and claim 3 of application AU are designated to correspond to the count. No preliminary motions are filed. A judgment is entered in favor of applicant AT on the sole count. Applicant AU would be estopped to obtain a patent containing a claim to benzene, because applicant AU failed to file a preliminary motion seeking to add a count to benzene. Applicant AU would not be estopped to obtain a patent containing claims to toluene, because applicant AU could not have properly moved to add a count to toluene (toluene was not disclosed by applicant AT). However, to obtain a patent containing claims to toluene, applicant AU would have to establish that toluene is a separate patentable invention from solvent. See *Smith v. Watson, 95 U.S. App. D.C. 52, 218 F.2d 863, 104 USPQ 160 (1955).*

Under § 1.659, as proposed, the Board would be able to make recommendations to examiners and the

# United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

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Appealed from: United States District Court for the Eastern District of Virginia

Senior Judge James C. Cacheris

# United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

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DECIDED: March 20, 2009

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Before RADER, BRYSON and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge PROST. Concurring opinion filed by Circuit Judge BRYSON. Opinion concurring in part and dissenting in part filed by Circuit Judge RADER.

PROST, Circuit Judge.

The United States Patent and Trademark Office ("USPTO") appeals the April 1, 2008 decision of the United States District Court for the Eastern District of Virginia granting summary judgment that four recently promulgated rules exceed the scope of

the USPTO's rulemaking authority. Because we conclude that the four rules are procedural, but that Rule 78 is inconsistent with 35 U.S.C. § 120, we affirm-in-part, vacate-in-part, and remand.

## I. BACKGROUND

In January 2006, the USPTO initiated two related notice and comment rulemaking proceedings. After receiving and considering the public comments, the USPTO issued the new rules on August 21, 2007, with an effective date of November 1, 2007. Changes to Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications, 72 Fed. Reg. 46,716 (Aug. 21, 2007). Four of the new rules (collectively, the "Final Rules") are at issue in this appeal.

Two of the new rules, Final Rule 78 and Final Rule 114, pertain to continuation applications and requests for continued examination ("RCEs") and were issued to address the "large and growing backlog of unexamined patent applications." Id. at 46,717. Final Rule 78 governs the availability of continuation and continuation-in-part applications.[1] Under the rule, an applicant is entitled to file two continuation applications as a matter of right. 37 C.F.R. § 1.78(d)(1)(i). If an applicant wishes to pursue more than two continuation applications, he must file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application." Id. § 1.78(d)(1)(vi). If the applicant cannot make the requisite showing, the USPTO will accept the application

[1] For a discussion of the problems created by continuation applications, see Mark A. Lemley & Kimberly A. Moore, Ending Abuse of Patent Continuations, 84 B.U. L. Rev. 63, 71-83 (2004).

for examination but will "refuse to enter, or will delete if present, any specific reference to a prior-filed application." Id. § 1.78(d)(1). The effect of this is to remove the application from the scope of 35 U.S.C. § 120, which would otherwise entitle the application to the filing date of the prior-filed application. Final Rule 114 provides for similar treatment of RCEs. Under the rule, an applicant is allowed one RCE as a matter of right. Id. § 1.114(f). For each additional RCE, the applicant must file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application." Id. § 1.114(g). The limitation on RCEs is applied on the basis of application families, rather than individual applications. Id. § 1.114(f).

The two other rules, Final Rule 75 and Final Rule 265, are intended to address the USPTO's difficulty in examining applications that contain a large number of claims. 72 Fed. Reg. at 46,721. Final Rule 75 requires an applicant who submits either more than five independent claims or twenty-five total claims to provide the examiner with information in an examination support document ("ESD"). 37 C.F.R. § 1.75(b)(1). The requirements for ESDs are set forth in Final Rule 265. To comply with Final Rule 265, an applicant must conduct a preexamination prior art search, provide a list of the most relevant references, identify which limitations are disclosed by each reference, explain how each independent claim is patentable over the references, and show where in the specification each limitation is disclosed in accordance with 35 U.S.C. § 112, ¶ 1. Id. § 1.265(a).

Shortly after the Final Rules were published in the Federal Register, Triantafyllos Tafas, SmithKline Beecham Corporation, and Glaxo Group Limited (collectively,

"Appellees") filed suit against the USPTO. On October 31, 2007, the district court preliminarily enjoined enforcement of the Final Rules. Tafas v. Dudas, 511 F. Supp. 2d 652 (E.D. Va. 2007) ("Tafas I"). Appellees then moved for summary judgment that the Final Rules are invalid and sought a permanent injunction against their enforcement. Appellees' summary judgment motions alleged that the Final Rules were impermissibly substantive, inconsistent with law, arbitrary and capricious, incomprehensibly vague, impermissibly retroactive, and procedurally defective.

The district court agreed with Appellees that the Final Rules were "substantive rules that change existing law and alter the rights of applicants such as [Appellees] under the Patent Act." Tafas v. Dudas, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008) ("Tafas II"). Specifically, the district court found that the Final Rules created limits on continuation applications, RCEs, and claims that were inconsistent with several sections of the Patent Act, as well as precedent from this court and its predecessor, the Court of Customs and Patent Appeals. The district court concluded that because the USPTO lacks substantive rulemaking authority under Merck & Co., Inc. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996), the Final Rules exceed the USPTO's statutory jurisdiction in violation of 5 U.S.C. § 706(2). Tafas II, 541 F. Supp. 2d at 814. Accordingly, the district court granted Appellees' motion for summary judgment that the Final Rules are invalid.[2]

[2] The district court fully disposed of the case on the grounds that the Final Rules are substantive. As part of its analysis, the court partially considered whether the rules conflict with the law. Apart from this, the court did not address Appellees' other arguments.

The USPTO timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

## II. DISCUSSION

"We review the district court's grant of summary judgment without deference, reapplying the same standard as the district court." Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1281 (Fed. Cir. 2005). Summary judgment is appropriate only if the record shows "there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); see also Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). Under the Administrative Procedure Act ("APA"), the reviewing court shall set aside agency action if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A)-(D).

The USPTO alleges two main errors in the district court's analysis. First, the USPTO argues that the court erred by failing to give the agency's interpretation of 35 U.S.C. § 2(b)(2)'s grant of rulemaking authority proper deference under Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The USPTO contends that under a proper application of Chevron, the inquiry in this case is not whether the rules are substantive or procedural, but whether they fit within a reasonable interpretation of § 2(b)(2), which gives the USPTO authority to "establish regulations, not inconsistent with law, which . . . shall govern the conduct of proceedings in the Office . . . [and] facilitate and expedite the processing of patent applications." 35 U.S.C.

§ 2(b)(2). Second, the USPTO argues that even if the substantive/procedural framework is applicable, the Final Rules are clearly procedural. According to the USPTO, the district court's erroneous conclusion that the Final Rules are substantive was the result of a mistaken interpretation of the rules, misapplication of the statutes and precedent, and failure to properly give deference to the USPTO's interpretation of the Patent Act under Chevron and National Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967 (2005). We address each argument in turn.

A. The Scope of the USPTO's Rulemaking Authority

Section 2(b)(2) of the Patent Act gives the USPTO authority to

> establish regulations, not inconsistent with law, which . . . (A) shall govern the conduct of proceedings in the office; . . . (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically . . . (D) may govern the recognition and conduct of agents, attorneys, or other persons representing applicants or other parties before the Office . . . .

35 U.S.C. § 2(b)(2). Additionally, 35 U.S.C. § 132(b) requires the USPTO to "prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." The USPTO asserts that this case should be fully resolved in its favor based on the language of these two sections. So long as the Final Rules fall within the scope of either § 2(b)(2) or § 132(b), the USPTO contends, they do not exceed its rulemaking authority. Further, the USPTO argues that this court has previously recognized that the USPTO's interpretation of its rulemaking authority under § 2(b)(2) is entitled to Chevron deference. See, e.g., Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006), cert. denied, 127 S. Ct. 1246 (2007). The USPTO thus argues that the district court erred by grafting a distinction between substantive and procedural rules onto the plain language of § 2(b)(2) without according any deference to

the USPTO's interpretation. Appellees maintain that the district court correctly decided that the USPTO cannot make substantive rules and no deference is due until it is established that the USPTO has acted within its statutory authority. We begin by addressing whether the USPTO's authority is subject to the substantive/procedural distinction, and then examine the proper level of deference to be given in this case.

1. The Substantive/Procedural Distinction

We agree with the district court that § 2(b)(2) "does not vest the USPTO with any general substantive rulemaking power." Tafas II, 541 F. Supp. 2d at 811. This principle is amply supported by our precedent. See, e.g., Animal Legal Def. Fund v. Quigg, 932 F.2d 920, 930 (Fed. Cir. 1991) ("A substantive declaration with regard to the Commissioner's interpretation of the patent statutes, whether it be section 101, 102, 103, 112 or other section, does not fall within the usual interpretation of [the language in section 6, the predecessor of § 2(b)(2)]."); Merck, 80 F.3d at 1550 (Section 6 "does NOT grant the Commissioner the authority to issue substantive rules. Because Congress has not vested the Commissioner with any general substantive rulemaking power, the Final Determination at issue in this case cannot possibly have the force and effect of law." (citations and quotation marks omitted)); Cooper Techs. Co. v. Dudas, 536 F.3d 1330, 1335 (Fed. Cir. 2008) ("To comply with section 2(b)(2)(A), a Patent Office rule must be 'procedural'—i.e., it must 'govern the conduct of proceedings in the Office.'").

Additionally, when Merck was decided, 35 U.S.C. § 6(a) gave the USPTO authority to establish regulations that govern "the conduct of proceedings." We agree with Appellees that Congress's decision to replace § 6(a) with the current § 2(b)(2), which contains the same grant of authority to regulate "the conduct of proceedings in

the Office" is indicative that Congress did not intend to give the USPTO substantive rulemaking authority.[3] See Lorillard v. Pons, 434 U.S. 575, 580 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.").

Accordingly, we must reject the USPTO's argument that the substantive/procedural distinction is immaterial in this case.

2. Chevron Deference

The USPTO argues that the district court erred by failing to accord Chevron deference at two stages of its analysis. First, Chevron deference is allegedly required for the threshold question of whether § 2(b)(2) vests the USPTO with substantive rulemaking authority. Second, the USPTO maintains that its interpretation of various sections of the Patent Act, and its accordant belief that the Final Rules are consistent therewith, is also entitled to deference. We cannot accept the USPTO's first argument, but we conclude that the USPTO's interpretations of statutes that pertain to the USPTO's delegated authority are entitled to Chevron deference.

Before a reviewing court grants Chevron deference, it must first determine whether the agency's interpretation of the statute was made pursuant to "a congressional delegation of administrative authority." Adams Fruit Co. v. Barrett, 494 U.S. 638, 649 (1990). This threshold inquiry, which has been dubbed Chevron "step

[3] While Cooper Technologies, 536 F.3d at 1336-37, casts doubt on the district court's view that § 2(b)(2)(B) requires notice and comment rulemaking for all USPTO rules, we nevertheless agree that Congress did not hide the "elephant" of substantive rulemaking authority in the "mousehole" of § 2(b)(2)(B). See Tafas II, 541 F. Supp. 2d at 812; see also Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 468 (2001).

zero," determines "whether courts should turn to the Chevron framework at all." Thomas W. Merrill & Kristin E. Hickman, Chevron's Domain, 89 Geo. L.J. 833, 836 (2001). Cases from this court have concluded, in different circumstances, that an agency's determination of the scope of its own authority is not entitled to Chevron deference. See, e.g., Borlem S.A.-Empreedimentos Industriais v. United States, 913 F.2d 933, 937 (Fed. Cir. 1990) ("A court is indeed obligated to give deference to an agency acting within its scope of responsibility. . . . [However,] such deference should not apply when the issue is the legal scope of an agency's authority."). A majority of the Supreme Court has not yet spoken to this issue. Cf. Miss. Power & Light Co. v. Miss. ex rel. Moore, 487 U.S. 354, 380 (1988) (Scalia, J., concurring) ("Contrary to the dissent, we have held that this rule of deference applies to an agency's interpretation of a statute designed to confine its authority." (citation omitted)) with id. at 386 (Brennan, J., dissenting) ("I cannot, however, agree with Justice SCALIA's conclusion that courts must defer to an agency's statutory construction even where, as here, the statute is designed to confine the scope of the agency's jurisdiction to the areas Congress intended it to occupy."); see also N. Ill. Steel Supply Co. v. Sec'y of Labor, 294 F.3d 844, 846-47 (7th Cir. 2002) (recognizing Justice Scalia's concurrence in Mississippi Power, stating that "the Supreme Court has not definitively ruled on the issue," and declining to grant deference to the agency's determination of its own jurisdiction).

We are not persuaded by the USPTO's arguments in this case that Chevron deference should be extended to the issue of whether § 2(b)(2) provides substantive rulemaking authority. To the extent the USPTO relies on Federal Circuit cases that give Chevron deference to the USPTO's interpretation of certain phrases present in

§ 2(b)(2), we conclude that those cases are inapposite because they involve judicial review of rules that are procedural, and thus within the judicially interpreted scope of the USPTO's rulemaking authority. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007) (deferring to the USPTO's interpretation of the phrase "before the Office" on review of the USPTO's decision to discipline an attorney for misconduct); Lacavera, 441 F.3d at 1383 (deferring to the USPTO's interpretation of "necessary qualifications" to be required of individuals who seek recognition to practice before the USPTO); Stevens v. Tamai, 366 F.3d 1325, 1333-34 (Fed. Cir. 2004) ("In view of the reasonableness of the Office's rules governing the procedure in patent interferences, and the substantial deference we accord such rules . . . ." (emphasis added)). Because we decline to accord deference with respect to the question of whether the USPTO has substantive rulemaking authority, our conclusion above that the USPTO does not have such authority is unaffected by Chevron.

The next question is the level of deference to be given to USPTO rules that are within the scope of the USPTO's delegated authority, i.e., procedural rules promulgated under § 2(b)(2) or § 132(b). Our precedent is clear that the Chevron framework is applicable to review of these rules. See, e.g., Cooper Techs., 536 F.3d at 1337; Bender, 490 F.3d at 1368; Lacavera, 441 F.3d at 1383; Stevens, 366 F.3d at 1333; Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1425 (Fed. Cir. 1988). Thus, on review of a procedural rule that has been issued by the USPTO, we will give Chevron deference to the USPTO's interpretation of statutory provisions that relate to the exercise of delegated authority. See Cooper Techs., 536 F.3d at 1337 ("Because the Patent Office is specifically charged with administering statutory provisions relating to 'the conduct of

proceedings in the Office,' 35 U.S.C. § 2(a)(2)(A), we give Chevron deference to its interpretations of those provisions.").

B. Classification of the Final Rules

With the analytical framework established, we turn to whether the Final Rules are substantive or procedural. The parties agree that the USPTO has authority under § 2(b)(2) to promulgate procedural rules. They vigorously disagree, however, as to how the boundary between "substantive" and "procedural" rules should be defined.

The district court relied on Chrysler Corp. v. Brown, 441 U.S. 281, 302 (1979), to define as substantive "any rule that 'affect[s] individual rights and obligations.'" Tafas II, 541 F. Supp. 2d at 814. We do not read Chrysler to create such a broad and absolute rule. In the portion of Chrysler cited by the district court, the Court simply "noted a characteristic inherent in the concept of a 'substantive rule'" and identified "an important touchstone for distinguishing those rules that may be 'binding' or have the 'force of law.'" 441 U.S. at 302. Substantive rules certainly "affect individual rights and obligations," but that inquiry does not necessarily distinguish most procedural requirements, which will also "affect individual rights and obligations." The Supreme Court itself made this observation when drawing the line between "substance" and "procedure" in the context of the Rules Enabling Act. See Hanna v. Plumer, 380 U.S. 460, 464-65 (1965) ("Undoubtedly most alterations of the rules of practice and procedure may and often do affect the rights of litigants."). This court's predecessor made the same observation. See In re Van Ornum, 686 F.2d 937, 945 (CCPA 1982) ("True, the rule is substantive in that it relates to a condition under which a patent will be granted which otherwise would have to be denied for double patenting. Much of the

content of the PTO rules is 'substantive' in this respect."). While this court has previously evaluated USPTO rules in terms of whether they "affect individual rights and obligations," it has done so in the process of distinguishing between "interpretive" and "substantive" rules. See Animal Legal Def. Fund, 932 F.2d at 927; Cooper Techs., 536 F.3d at 1336. We agree, therefore, with the USPTO that while the inquiry set forth in Chrysler and used in Animal Legal Defense Fund and Cooper Technologies may be useful in defining the boundary between interpretive and substantive rules, it is not dispositive on the issue of whether the Final Rules are procedural.

In addition to Chrysler, the parties cite several cases from the D.C. Circuit that have addressed the boundaries of substantive rules.[4] In American Hospital Ass'n v. Bowen, the D.C. Circuit defined substantive rules, as contrasted with interpretive rules, as those which "grant rights, impose obligations, or produce other significant effects on private interests, or which effect a change in existing law or policy." 834 F.2d 1037, 1045 (D.C. Cir. 1987) (citations and quotation marks omitted). With respect to the distinction between procedural and substantive rules, Bowen suggested that substantive rules "encode[] a substantive value judgment or put[] a stamp of approval or disapproval on a given type of behavior." Id. at 1047. However, the D.C. Circuit has also noted that, "[o]f course, procedure impacts on outcomes and thus can virtually

[4] The concurrence and dissent each correctly point out that this is not a case arising under the notice and comment rulemaking provision of the APA. Therefore, this case does not turn on whether the rules are "procedural" within the meaning of 5 U.S.C. § 553(b)(A). We recognize that the definitions of "substance" and "procedure" in the notice and comment rulemaking context may embody policy considerations that are not coextensive with the considerations at issue in this case. However, we find that these cases are nevertheless helpful to the task of drawing a similar line between "substance" and "procedure" in the present case.

always be described as affecting substance." JEM Broad. Co. v. FCC, 22 F.3d 320, 326 (D.C. Cir. 1994) (quoting Air Transp. Ass'n of Am. v. Dep't of Transp., 900 F.2d 369, 383 (D.C. Cir. 1990) (Silberman, J., dissenting)). Similarly, the D.C. Circuit held in Public Citizen v. Department of State that although the State Department's decision not to search documents produced after the date of a Freedom of Information Act request represented a "judgment about procedural efficiency," such a judgment does not "convert a procedural rule into a substantive one." 276 F.3d 634, 641 (D.C. Cir. 2002) (quotation marks omitted). Thus, the D.C. Circuit has considered many of the issues underlying the present case and has understandably hesitated to adopt a conclusive test for when rules cross the line between procedure and substance.

We are most persuaded in this case by the D.C. Circuit's approach in JEM. At issue in that case were "hard look" rules adopted by the Federal Communications Commission ("FCC") in response to a significant number of "carelessly prepared and speculative applications" for broadcasting licenses. 22 F.3d at 327. Under those rules, applications that either failed to include necessary information or contained incorrect or inconsistent information that could not be "resolved within the confines of the application and with a high degree of confidence" were dismissed with no opportunity to cure the defect. Id. at 322. The D.C. Circuit rejected JEM's contention that the rules were substantive because they "deprive[d] license applicants of the opportunity to correct errors or defects in their filings." Id. at 327. In doing so, the court noted that a "critical feature of the procedural exception [in section 553 of the APA] is that it covers agency actions that do not themselves alter the rights or interests of parties, although [they] may alter the manner in which the parties present themselves or their viewpoints to the

agency." Id. at 326 (emphasis added) (quotation marks omitted). The "critical fact" that was "fatal to JEM's claim," the court held, was that the "hard look" rules "did not change the substantive standards by which the FCC evaluates license applications." Id. at 327. The court recognized that the rules could result in the loss of substantive rights, but found that they were nonetheless procedural because they did not "foreclose effective opportunity to make one's case on the merits." Id. at 327-28 (quoting Lamoille Valley R.R. Co. v. Interstate Commerce Comm'n, 711 F.2d 295, 328 (D.C. Cir. 1983)).

While we do not purport to set forth a definitive rule for distinguishing between substance and procedure in this case, we conclude that the Final Rules challenged in this case are procedural. In essence, they govern the timing of and materials that must be submitted with patent applications. The Final Rules may "alter the manner in which the parties present . . . their viewpoints" to the USPTO, but they do not, on their face, "foreclose effective opportunity" to present patent applications for examination. JEM, 22 F.3d at 326, 328.

Final Rules 78 and 114 provide requirements for when continuation applications will be accepted and RCEs will be granted. The D.C. Circuit has recognized time schedules as being "definitely at the procedural end of a spectrum running from 'procedural' to 'substantive.'" Lamoille, 711 F.2d at 328. Applicants who include in each continuation application all amendments, arguments, and evidence available at the time of filing will not be limited by Final Rule 78. Similarly, applicants who diligently present all of their amendments, arguments, and evidence as soon as possible during prosecution will be granted as many RCEs as they require. Thus, applications that are submitted in compliance with these timing requirements will be fully examined and given

all of the benefits provided by the Patent Act. See JEM, 22 F.3d at 327. We do not believe that requiring applicants to raise all then-available amendments, arguments, and evidence by the second continuation application or the first RCE is so significant a burden that applicants will be effectively foreclosed from obtaining the patent rights to which they are entitled. See Lamoille, 711 F.2d at 328.

We are of course aware that the impact of Final Rules 78 and 114 will be largely dependent on how the USPTO interprets when amendments, arguments, and evidence "could not have been submitted during the prosecution of the prior-filed application" or "prior to the close of prosecution." 37 C.F.R. §§ 1.78, 1.114(g). When the Final Rules were published, the USPTO also published responses to questions raised during the notice and comment proceedings, many of which addressed specific scenarios under which continuation applications and RCEs may be requested. See, e.g., 72 Fed. Reg. at 46,769-77. The district court relied on the contents of these responses to conclude that the USPTO "intends to deny additional applications in almost all circumstances" such that Final Rules 78 and 114 are in fact "hard limits" on continuation applications and RCEs. Tafas II, 541 F. Supp. 2d at 814-16. Appellees and several amici encourage us to adopt this analysis. However, we decline to rely on these responses, which are not binding on the USPTO and often either state that decisions will be made on a "case-by-case basis" or speak in terms of whether it is "likely" or "unlikely" that a petition will be granted, to justify a decision that the Final Rules, as actually codified in the Code of Federal Regulations, are facially invalid. These responses are not binding on the courts, which will be free to entertain challenges to the USPTO's application of

the Final Rules, including its view of when amendments, arguments, and evidence could not have been submitted earlier, under the standard set forth in 5 U.S.C. § 706.

With respect to the ESD requirement, Final Rules 75 and 265 require applicants who present more than five independent claims or twenty-five total claims to provide the examiner with information about the prior art and why they believe the claims are patentable over it. Once a satisfactory ESD is submitted, examination will proceed in precisely the same manner as it would have in the absence of the rule. It is important to note that an examiner is not permitted to substantively reject claims on grounds that the ESD did not prove that the claims are patentable. While an examiner is of course free to base a rejection on references disclosed in the ESD, he must nevertheless set forth his own prima facie case of unpatentability. Thus, while the rule may put a burden of production on the applicant, the examiner maintains the burden of persuasion.

This court has previously recognized the validity of two USPTO rules that place upon applicants the burden of submitting information in response to an examiner's request. See Star Fruits, 393 F.3d at 1282-84 (Rule 105); see also In re Epstein, 32 F.3d 1559, 1570 (Fed. Cir. 1994) (Plager, J., concurring) (Rule 56). Rather than arguing that Rules 56 and 105 are invalid, Appellees attempt to distinguish them from the Final Rules because they only pertain to information that is already known by or readily available to the applicant. GlaxoSmithKline Br. 48. While we recognize this difference, we decline to draw the line between procedure and substance on these grounds alone. A procedural rule does not become substantive simply because it requires the applicant to exert more effort to comply, so long as the effort required is not

so great that it effectively forecloses the possibility of compliance. See Lamoille, 711 F.2d at 328.

Appellees and amici argue that the ESD requirement is in fact so draconian that compliance would be both impossible and extraordinarily foolish. With respect to impossibility, Appellees argue that Rule 265 requires a "world-wide search of prior art without regard to scope, time, or cost." GlaxoSmithKline Br. 46. We do not find such a requirement on the face of Final Rule 265. Rather, the rule describes a preexamination search of "U.S. patents and patent application publications, foreign patent documents, and non-patent literature," and requests specific details about the scope of the search. 37 C.F.R. § 1.265(a)-(b). The text of the rule does not demand that the applicant review every reference that fits into one of those categories, regardless of its location or accessibility. Instead, it requires applicants to conduct and document a "search." A "search" of "non-patent literature" does not necessarily require a visit to every library in every corner of the world. A reasonable, cost-effective search is just as much a "search" as the search described by Appellees. While the text of the rules sets forth a facially reasonable procedural requirement,[5] we are mindful of the possibility that the USPTO may in some cases attempt to apply the rules in a way that makes compliance essentially impossible and substantively deprives applicants of their rights. In such cases, judicial review will be available under 5 U.S.C. § 706.

[5] To the extent the USPTO has commented about its intended application of the ESD requirement, either in public speeches or in the Federal Register, we make the same observation made above: these comments do not bind the USPTO with respect to its future actions, and they do not affect the courts' ability to resolve challenges to specific applications of the rules.

Search scope aside, several amici argue that submitting an ESD is so wrought with peril that sane applicants will be absolutely limited to five independent claims and twenty-five total claims. These arguments have two components. The first is that even the most diligently prepared ESD will inevitably open the applicant to inequitable conduct allegations that will entail costly litigation and a possible finding of unenforceability. We believe this concern is too speculative to void the rules and, in any event, is at its core a matter of inequitable conduct doctrine, not USPTO rulemaking authority. The reach of inequitable conduct is solely within the control of the courts, and the doctrine has obviously not yet been applied in the context of an ESD. We decline to decide that an otherwise valid USPTO rule that requires applicants to provide information is void because this court might in the future apply inequitable conduct doctrine in such a way that honest applicants who comply in good faith will nevertheless lose their patent rights. Under Kingsdown Medical Consultants, Ltd., v. Hollister, Inc., "'gross negligence' does not of itself justify an inference of intent to deceive." 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part). We recognize that the drafting of an ESD will entail browsing many references, that mistakes and omissions will inevitably occur, and that the courts will be asked to determine if there was inequitable conduct. However, doubt about the judiciary's ability to apply its own doctrine in a way that yields fair results and discourages frivolous allegations should not preclude the USPTO from promulgating rules that are within its statutory authority.

Second, several amici argue that ESDs will decrease the value of patent rights because the statements therein will limit claim scope through prosecution history estoppel. We do not believe applicants have a right to remain silent throughout

prosecution in order to maximize their advantage in later litigation. The Patent Act demonstrates that applicants are expected to be forthright about their inventions. Section 112 requires applicants to provide a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112, ¶ 1 (emphasis added). It also requires the application to "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." Id. § 112, ¶ 2 (emphasis added). This court has recognized that "[a]pplicants for patents have a duty to prosecute patent applications in the Patent Office with candor, good faith, and honesty." See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp., 488 F.3d 982, 999 (Fed. Cir. 2007). We are aware that some applicants attempt to say as little as possible during prosecution so that the precise boundaries of their claims will be open to argument as competitors' products enter the market and new prior art references are found during litigation. However, we consider this practice to be a burden on the patent system, not a right that can be invoked to void the Final Rules.

Having concluded our discussion of why the Final Rules are procedural, it is important to note one way in which our substantive/procedural analysis differs from that of the district court. While the district court initially stated that it need not decide "whether the Final Rules run contrary to the Act's provisions," it did just that throughout its discussion of the substantive nature of the rules. Tafas II, 541 F. Supp. 2d at 811 n.4, 814-17. The district court in large part based its conclusion that the Final Rules are substantive on grounds that they deprived applicants of rights guaranteed by various

sections of the Patent Act. Id. at 814-17. Because, as discussed above, we do not believe the test the district court distilled from Chrysler—whether the rules "affect individual rights and obligations"—is correct, we similarly conclude that consistency with the Patent Act is not the touchstone of whether the rules are procedural or substantive. For example, 37 C.F.R. § 1.52(a)(1)(i) requires most documents submitted to the USPTO to be printed on white paper. No one would dispute that this rule is procedural. If Congress then created a new section of the Patent Act that required all documents to be printed on yellow paper, § 1.52(a)(1)(i) would certainly become invalid. However, the reason for its invalidity would be that it is inconsistent with an express provision of the Act, not that the new statute transformed it from a procedural rule into a substantive one. Similarly, the USPTO's "determination" at issue in Merck was found to be substantive without regard to whether it conflicted with existing law. See 80 F.3d at 1550. Therefore, we find it necessary to separate the question of whether the Final Rules are procedural from the question of their consistency with the Patent Act. Having addressed the former, we now turn to the district court's view of the latter.

C. Consistency with the Patent Act

We address here the specific conflicts that the district court identified and relied upon in its opinion. Because each of the rules is procedural, we must, as discussed above, give Chevron deference to the USPTO's interpretation of the provisions of the Patent Act that relate to "proceedings in the Office." Cooper Techs., 536 F.3d at 1337. For such provisions, we must first determine "whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously

expressed intent of Congress." Chevron, 467 U.S. at 842-43. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Id. at 843. Even if a court has previously resolved the specific question at issue, the agency's construction must be adopted unless "the prior court decision holds that its construction follows from the unambiguous terms of the statute and thus leaves no room for agency discretion." Brand X, 545 U.S. at 982.

1. Final Rule 78

The district court found that Final Rule 78's requirement for the third and subsequent continuation applications was inconsistent with the text of 35 U.S.C. § 120 and this court's precedent. Section 120, with emphasis and bracketed enumeration added, provides that:

> An application for patent for [1] an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is [2] filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, [3] if filed before the patenting or abandonment of or termination of proceedings on [3a] the first application or on [3b] an application similarly entitled to the benefit of the filing date of the first application and [4] if it contains or is amended to contain a specific reference to the earlier filed application. No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director may consider the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director may establish procedures, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

The district court concluded that Final Rule 78 was inconsistent with the statutory mandate that qualifying applications "shall have" the benefit of the priority date of the

initial application. Tafas II, 541 F. Supp. 2d at 814. Additionally, the district court cited this court's predecessor for the propositions that "there is no statutory basis for fixing an arbitrary limit to the number of [continuing] applications," id. (quoting In re Henriksen, 399 F.2d 253, 254 (CCPA 1968)) (alteration provided by the district court), and that "a limit upon continuing applications is a matter of policy for the Congress," id. (quoting In re Hogan, 559 F.2d 595, 604 n.13 (CCPA 1977)). In light of the USPTO's presumed "inten[t] to deny additional applications in almost all circumstances," the district court found that Final Rule 78 set forth a "mechanical rule" that "changes existing law and deprives applicants of their valuable rights under 35 U.S.C. § 120 to an unlimited number of continuation and continuation-in-part applications as a matter of right." Id. at 815.

We agree with the district court that Final Rule 78 is inconsistent with § 120, although we rely on narrower grounds. Section 120 unambiguously states that an application that meets four requirements "shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. § 120 (emphasis added). These requirements, which correspond to the bracketed enumeration above, include [1] the invention claimed in the application must have been properly disclosed in a prior-filed application; [2] the application must have been filed by inventor(s) named on the prior-filed application; [3] the application must have been "filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application"; and [4] the application must contain or be amended to contain a specific reference to the prior-filed application. The use of "shall" indicates that these

are the exclusive requirements, and that all applications that meet these requirements must receive the benefit provided by § 120. See Transco Prods., Inc. v. Performance Contracting, Inc., 38 F.3d 551, 556 (Fed. Cir. 1994) ("The plain and unambiguous meaning of section 120 is that any application fulfilling the requirements therein 'shall have the same effect' as if filed on the date of the application upon which it claims priority."). Thus, Rule 78 is invalid because it attempts to add an additional requirement—that the application not contain amendments, arguments, or evidence that could have been submitted earlier—that is foreclosed by the statute. Because the statute is clear and unambiguous with respect to this issue, the USPTO's reliance on Chevron and Brand X is unavailing.

As amici, several intellectual property and administrative law professors argue that Henriksen expressly recognized ambiguity in § 120. Accordingly, they argue, the USPTO's interpretation is entitled to deference under Brand X. We agree that the Henriksen court's approach of delving into the legislative history, which it noted was "somewhat inconclusive," indicates that the text of the statute contains some ambiguity. See Henriksen, 399 F.2d at 256-58. However, the issue in Henriksen was whether there was a "limit to the number of prior applications through which a chain of copendency may be traced to obtain the benefit of the filing date of the earliest of a chain of copending applications." Id. at 254. In other words, the question related to the permissible length of a chain of serial continuation applications, not the total number of continuation applications that may be filed. Specifically, the dispute was over the meaning of clause [3b] identified above—"an application similarly entitled to the benefit of the filing date of the first application." Id. at 260-61. The ambiguity in clause [3b],

however, cannot save Final Rule 78. The Final Rule limits continuation applications on the basis of the total number of such applications previously filed, not on the length of a given serial chain of such applications. 37 C.F.R. § 1.78(d)(1)(i)(B). By its terms, Final Rule 78 would apply to an applicant who seeks to file three continuation applications while the first application is still pending, even though each of these applications falls squarely within clause [3a] and would thus satisfy any reasonable interpretation of clause [3] and the rest of § 120. Therefore, while we must defer to the USPTO's reasonable interpretation of clause [3], there is no such interpretation that preserves the validity of Final Rule 78.

Finally, the USPTO's reliance on In re Bogese, 303 F.3d 1362 (Fed. Cir. 2002), is unavailing. In Bogese, this court affirmed the Board of Patent Appeals and Interferences's rejection of claims in the applicant's continuation application on the grounds of extraordinary delay in prosecution. 303 F.3d at 1366. The applicant had submitted "twelve continuation applications over an eight-year period and did not substantively advance prosecution of [the application at issue] when required and given an opportunity to do so." Id. at 1369. According to the USPTO, Bogese "forecloses any argument that the conditions enumerated in Section 120 for making a priority claim are exclusive." USPTO Br. 45. This is so, it contends, because the opinion recognized that "[t]he PTO has inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Bogese, 303 F.3d at 1368. We do not read the opinion so broadly. The holding of Bogese was that "the PTO has authority to order forfeiture of rights for unreasonable delay." Id. at 1369. However, Bogese does not extend that power

beyond the boundaries of prosecution history laches, which was upheld as an equitable defense to infringement in Symbol Technologies, Inc. v. Lemelson Medical, 277 F.3d 1361 (Fed. Cir. 2002) ("Symbol II"). Rather, the panel recognized that "the PTO has the authority to reject patent applications for patents that would be unenforceable under our holding in [Symbol II]." Bogese, 303 F.3d at 1367. We agree that the USPTO has "inherent authority to govern procedure before the PTO, and that authority allows it to set reasonable deadlines and requirements for the prosecution of applications." Id. at 1368. However, under Bogese, the USPTO cannot set requirements that conflict with § 120 unless those requirements comport with a proper application of prosecution history laches. There are no "firm guidelines" for determining when prosecution laches exists. Symbol Techs., Inc. v. Lemelson Med. Educ. & Research Found., 422 F.3d 1378, 1385 (Fed. Cir. 2005) ("Symbol IV"). However, it is limited to cases of "unreasonable and unexplained delay in prosecution." Id. at 1384-85. We need not address the precise boundaries of the USPTO's authority to promulgate rules under Bogese because Final Rule 78 is far too restrictive to fall within the scope of prosecution history laches. The rule operates on an applicant's third continuation application without regard to when it was filed, even if the delay is significantly shorter than any of the delays in our prior prosecution history laches cases. See, e.g., Symbol IV, 422 F.3d at 1386 (eighteen to thirty-nine years elapsed between filing and issuance); Bogese, 303 F.3d at 1369 (eight years without the applicant substantively advancing prosecution). The rule simply captures too many applications that would not be even remotely susceptible to a prosecution history laches challenge. Therefore, Final Rule 78 is not a proper use of the USPTO's authority under Bogese to apply prosecution history laches.

2. Final Rule 114

The district court found that Final Rule 114, which governs the availability of RCEs, conflicts with the Patent Act in two ways. The first was that it "places a limit on RCEs as of right on the basis of application family, rather than on the basis of each individual application, whether it be a parent application or a continuation or continuation-in-part application." Tafas II, 541 F. Supp. 2d at 815. The district court found that this was inconsistent with 35 U.S.C. § 132, which uses the singular form of "application." Additionally, the court noted Congress's "pronouncement, upon enacting Section 132(b), that the RCE provisions 'shall apply to all applications' filed on or after June 8, 1995." Id. (quoting American Inventors Protection Act of 1999, Pub. L. No. 106-113, § 4405(b)(1), 113 Stat. 1501, 1501A-560 to 1501A-561 (1999)). Second, the court found that § 132(b)'s mandate that "[t]he director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant" gave applicants the right to "an unlimited number of RCEs per application at their discretion." Id. This right, the court held, was violated by Final Rule 114. Id.

We do not find that § 132 unambiguously dictates that its provisions be applied on a per application basis. Cf. Henriksen, 399 F.2d at 258 ("So read, 'an application' does not necessarily refer only to a single application."); 1 U.S.C. § 1 ("[W]ords importing the singular include and apply to several persons, parties, or things . . . ."). Therefore, because we defer to the USPTO's reasonable interpretation of the statute, we conclude that Final Rule 114 can properly be applied on a per family basis. See Cooper Techs., 536 F.3d at 1337-38.

Appellees next argue that the use of "shall" in conjunction with the phrase "at the request of the applicant" in § 132(b) clearly shows that Congress intended RCEs to be unlimited and subject only to the applicant's discretion. GlaxoSmithKline Br. 40. We do not find the statute so clear. It is plausible that, as the USPTO suggests, § 132(b) simply directs the USPTO to "prescribe regulations" to govern the applicant's ability to request continued examination which must, in some circumstances, be granted. Under this reading, nothing prevents the USPTO from limiting the availability of the second and subsequent RCEs. Because § 132(b) does not unambiguously require the USPTO to grant unlimited RCEs, we defer to the USPTO's interpretation. See Cooper Techs., 536 F.3d at 1337-38.

Finally, Appellees argue that § 132(a) requires the USPTO to continue examination if "the applicant persists in his claim for a patent." Tafas Br. 32-33. Section 132(a) provides:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 132(a) (emphases added). The USPTO responds that this argument "reflects a misunderstanding of the relationship between subsections (a) and (b) [of § 132]." USPTO Br. 53. According to the USPTO, "[s]ubsection (a) provides for the 'reexamination' of an application at the applicant's request after the initial examination provided in section 131. In contrast, 'continued examination' under subsection (b) occurs after the reexamination provided for in subsection (a) is complete." Id. Section

132 does not define the difference between "continued examination" and "reexamination." Because we find the USPTO's explanation reasonable, we defer to its interpretation that § 132(a) does not require it to grant unlimited RCEs. See Cooper Techs., 536 F.3d at 1337-38. Under this interpretation, Final Rule 114 does not conflict with § 132(a).

3. Final Rules 75 and 265

The district court held that the ESD requirement violated 35 U.S.C. §§ 102, 103, 112, and 131, as well as this court's precedent that holds that applicants have no duty to search the prior art. The court began its analysis with § 112, ¶ 2's requirement that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." The district court held, and Appellees argue on appeal, that this language precludes the USPTO from putting an arbitrary limit on the number of claims in an application.

Subject to the arguable requirement that an applicant cannot "obscure" his invention by "undue multiplicity," our precedent does not suggest that there is a limit on the number of claims. In re Clark, 97 F.2d 628, 631 (CCPA 1938); see also In re Wakefield, 422 F.2d 897, 900 (CCPA 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims . . . ."); In re Chandler, 319 F.2d 211, 225 (CCPA 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). However, we need not decide whether the USPTO may impose a limit on the number of claims an applicant can

pursue because we do not find that the ESD requirement creates any such limit. Rather, it simply requires that an ESD be submitted if more than five independent or twenty-five total claims are included in certain sets of copending applications. Because we cannot, as discussed above, conclude that Final Rules 75 and 265, on their face, effectively foreclose applicants from successfully submitting ESDs, we similarly cannot conclude that these rules place an absolute limit on claim numbers in violation of § 112, ¶ 2.

The district court also found that Final Rules 75 and 265 went too far by requiring applicants to "conduct a broad search of patents, patent applications, and literature, and provide, among other things, a 'detailed explanation' of 'how each of the independent claims is patentable over the cited references.'" Tafas II, 541 F. Supp. 2d at 816 (quoting 37 C.F.R. § 1.265(a)). The court relied on several of this court's inequitable conduct cases that noted that, in general, there is "no duty to conduct a prior art search." Frazier v. Roessel Cine Photo Tech., Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005) (quoting FMC Corp. v. Hennessy Indus., Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987)); see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1351 n.4 (Fed. Cir. 2005). We agree with the USPTO that these cases do not speak to whether the USPTO may impose such a duty by regulation. Indeed, this court has already upheld the USPTO's authority to require from applicants "such information as may be reasonably necessary to properly examine or treat the matter." 37 C.F.R. § 1.105; see also Star Fruits, 393 F.3d at 1282-84. On this record, we see no persuasive reason to prohibit the USPTO from requesting the information required by Final Rule 265, even if the applicant must take action to acquire that information.

Finally, the district court found that Final Rules 75 and 265 improperly shift the burden away from the examiner and onto the applicant. Tafas II, 541 F. Supp. 2d at 817. The court relied on the language in § 102 that "[a] person shall be entitled to a patent unless," along with the requirement in § 131 that "[t]he director shall cause an examination to be made of the application." Id. Additionally, the district court noted that this court's precedent places the burden of putting forth a prima facie case of unpatentability on the USPTO. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We agree with the district court that the USPTO bears the initial burden of proving unpatentability, but disagree that the ESD requirement shifts that burden. Final Rules 75 and 265 do not require an applicant to make a prima facie case of patentability. While the rules require an applicant to conduct a prior art search and report his view of why the invention is patentable based on the results, the content of this disclosure does not change the standards by which the application is examined. An examiner cannot reject an application because he believes that the applicant failed to find the most material references or if he is otherwise not persuaded by the applicant's view of the prior art. Even under the new rules, the examiner must examine the application in accordance with § 131 and the applicant will be "entitled to a patent unless" the examiner can make a prima facie case of unpatentability. 35 U.S.C. § 102. Thus, while creating an additional procedural step for the submission of applications, the ESD requirement does not alter the ultimate burdens of the examiner or applicant during examination.

## III. CONCLUSION

For the foregoing reasons, we conclude that the Final Rules 75, 78, 114, and 265

are procedural rules that are within the scope of the USPTO's rulemaking authority. However, we find that Final Rule 78 conflicts with 35 U.S.C. § 120 and is thus invalid. Accordingly, we affirm the district court's grant of summary judgment that Final Rule 78 is invalid, vacate its grant of summary judgment with respect to Final Rules 75, 114, and 265, and remand for further proceedings consistent with this opinion.

Because of the complexity of this case and the numerous arguments presented on appeal and before the district court, we think it is important to expressly summarize what we believe remains for the district court on remand. This opinion does not decide any of the following issues: whether any of the Final Rules, either on their face or as applied in any specific circumstances, are arbitrary and capricious; whether any of the Final Rules conflict with the Patent Act in ways not specifically addressed in this opinion; whether all USPTO rulemaking is subject to notice and comment rulemaking under 5 U.S.C. § 553; whether any of the Final Rules are impermissibly vague; and whether the Final Rules are impermissibly retroactive.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

# United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff-Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs-Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants-Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in
consolidated case nos. 1:07-CV-846 and 1:07-CV-1008,
Senior Judge James C. Cacheris.

BRYSON, Circuit Judge, concurring.

I join Judge Prost's opinion but with the following observations.

1. In my view, the question whether the PTO is authorized to promulgate particular regulations does not turn on an abstract inquiry into whether a particular rule can be characterized as substantive, procedural, or interpretive. Instead, it calls on us to ask what Congress has empowered the PTO to do through rulemaking. Congress has not used the broadest available language in the statute that authorizes the PTO to engage in rulemaking, but neither has it used the narrowest. Congress could have

authorized the PTO to issue any regulations that are necessary or appropriate to administer the patent laws. See, e.g., 38 U.S.C. § 501 (Secretary of Veterans Affairs authorized to prescribe "all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department"); 5 U.S.C. § 8347(a) (Office of Personnel Management given authority to prescribe "such regulations as are necessary and proper to carry out [the Civil Service Retirement Act]"). Language of that sort would have given the PTO the very broad rulemaking authority. On the other hand, the PTO could have given no special authority to promulgate regulations, which would have had the effect of limiting the PTO to the narrow scope of 5 U.S.C. § 301, which allows all agencies to prescribe regulations "for the government of . . . [the] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." Congress did neither. Instead, it charted a middle course in 35 U.S.C. § 2(b), permitting the agency somewhat broader regulatory powers than are contemplated by section 301, but narrower than the broad "necessary or appropriate" rulemaking authority given to some other agencies.

Section 2(b)(2)(A) of the Patent Act vests the PTO with authority to promulgate regulations that "govern the conduct of proceedings in the Office." The subject matter that most clearly falls within the scope of that provision is the admission and discipline of attorneys practicing before the PTO. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007); Lacavera v. Dudas, 441 F.3d 1380, 1383 (Fed. Cir. 2006). Even apart from that context, however, we have taken a fairly expansive view of the scope of section 2(b)(2)(A). For example, in In re Sullivan, we held that section 2(b)(2)(A)

authorized the PTO to promulgate a regulation permitting conferences between an administrative patent judge and the parties to an interference proceeding. 362 F.3d 1324, 1328 (Fed. Cir. 2004). Also in the interference context, we held in Stevens v. Tamai that the PTO acted within its authority under section 2(b)(2)(A) when it promulgated regulations establishing that the movant has the burden of proof and duty of translating earlier filed documents into English, so as to show that the international application contains the same disclosure as the national stage application. 366 F.3d 1325, 1332 (Fed. Cir. 2004). Finally, in Cooper Technologies Co. v. Dudas, we held that the PTO was entitled to promulgate a regulation defining the term "original application" in a statutory provision that established the procedures for inter partes reexamination, and that the regulation was entitled to Chevron deference. 536 F.3d 1330, 1336-38 (Fed. Cir. 2008).

For essentially the reasons given by the majority opinion and in light of the above-cited authorities, I am satisfied that the regulations in this case are of the type that Congress authorized in section 2(b) of the Patent Act, as that provision has been construed by this court. While I think it is generally fair to characterize that statute as authorizing the promulgation of "procedural" regulations, however, I do not think it necessary, or particularly helpful, to consider whether those regulations would be deemed "substantive," "interpretive," or "procedural" either under section 4 of the Administrative Procedure Act, 5 U.S.C. § 553, or under statutory schemes applicable to other agencies.

The same approach seems to me to be called for in deciding whether the agency is entitled to deference with respect to the scope of its own authority. There, too, the

issue comes down to one of statutory construction—whether Congress left the boundaries of agency authority undefined and subject to refinement through the exercise of agency expertise, or whether Congress established a firm line, enforceable by courts, beyond which the agency could not venture. Normally, Congress defines the field of agency rulemaking authority in unambiguous terms that are readily applied by courts, so there is little reason to resort to Chevron-type analysis. In some instances, however, Congress has defined the agency's rulemaking jurisdiction using vague terms, or terms that call for agency interpretation, or even terms that expressly leave the scope of rulemaking authority to the agency to decide; in those cases, deference to the agency may be appropriate or even necessary. See, e.g., Bender v. Dudas, 490 F.3d 1361, 1368 (Fed. Cir. 2007) (deference given to PTO's interpretation of the phrase "before the Office" in section 2(b)(2)); Enercon GmbH v. Int'l Trade Comm'n, 151 F.3d 1376, 1380-81 (Fed. Cir. 1998) (deference given to ITC's interpretation of the word "sale" in the statute giving it jurisdiction, 15 U.S.C. § 1337); 5 U.S.C. § 7701(a) (authorizing Merit Systems Protection Board to act on appeals authorized by "any law, rule, or regulation"). In this case, it is unnecessary to decide whether deference would be due to the agency's interpretation of its own authority, as we conclude, even without deference, that the agency has authority to issue regulations of the sort issued in this case, subject to their consistency with the underlying statutory provisions being interpreted.

Because I agree with Judge Prost that the challenged regulations are within the scope of the authorization that Congress granted to the PTO in section 2(b), I likewise

conclude that the issue in this case comes down to whether the challenged regulations are consistent with other provisions of the Patent Act.

2. On the merits, the most difficult question in this case for me is whether Final Rule 78 is a valid regulation in light of 35 U.S.C. § 120. My colleagues conclude that it is invalid, although for different reasons. I agree that it is invalid for the reasons given by Judge Prost, although I think it is important to emphasize the narrow scope of the court's decision.

The court holds that Final Rule 78 is invalid because it limits the number of continuation applications that may be filed and applies that limit even if all of the continuation applications are filed while the first application is still pending. Section 120 plainly provides that any application that satisfies the other requirements of the statute and is "filed before the patenting or abandonment of or termination of proceedings on the first application" shall have the same effect "as though filed on the date of the prior application." 35 U.S.C. § 120. Therefore, a rule limiting the number of continuances co-pending with the first-filed application is necessarily contrary to the statute and invalid.

While that is a sufficient reason to invalidate Final Rule 78, it does not answer the question whether the rule is invalid as applied to serial continuances, i.e., a series of continuances in which each was co-pending with its immediate predecessor, but in which only the second in the series was co-pending with the first application. Under current law, all continuances in such a series, if they satisfy the other requirements of section 120, are deemed to have the same effective date as the first application. Rule 78 would change that practice.

The question whether the new Rule's restrictions on serial continuances would also be invalid is more complex than the question of the validity of restrictions on co-pending applications. As to serial continuances, section 120 provides that an application for continued prosecution is entitled to the benefit of an earlier priority date when it is co-pending with "an application similarly entitled to the benefit of the filing date of the first application." For the last 40 years, that portion of section 120 has been understood to confer upon patent applicants the right to file any number of successive continuation applications after the first application has been abandoned or issued as a patent. That was the construction of section 120 that our predecessor court adopted in 1968, overturning a Patent Office Board of Appeals decision to the contrary. In re Henriksen, 399 F.2d 253, 254 (CCPA 1968). It would not be unreasonable, however, to construe the phrase "an application similarly entitled" to mean an application that satisfies all the preceding requirements set forth in section 120, including the requirement of co-pendency with the initial application, which was the construction adopted by the Patent Office Board of Appeals in the Henriksen case. See Ex parte Henriksen, 154 U.S.P.Q. 53 (1966). In fact, the court in Henriksen acknowledged that a literal reading of the statutory language would lead to that conclusion. In re Henriksen, 399 F.2d at 256, 260-61 & n.18. Under that interpretation, applicants would be limited to a maximum of two continuations in series—one while the first application is pending and another while the first continuation is pending. Because the term "similarly entitled" admits of two reasonable constructions, the PTO could have adopted the narrower construction notwithstanding prior judicial precedent construing the statute in the

absence of a regulation interpreting the statutory language. See Nat'l Cable & Telecomms. Assn' v. Brand X Internet Servs., 545 U.S. 967, 982-86 (2005).

The court today properly strikes down Final Rule 78 because its restrictions on co-pending, or parallel, continuations is contrary to the plain language of section 120, which provides that such a co-pending continuation "shall" be given the same priority date as the original application and which contains no restriction on the numbers of such applications that are permitted. That is not to say, however, that a revised rule that addressed only serial continuances and limited such continuances to only two—the first co-pending with the original application and the second co-pending with the first—would be struck down as reflecting an impermissible interpretation of section 120. That is not a question that we need to—or should—decide today, but in my view it is important to emphasize that the question remains open.

# United States Court of Appeals for the Federal Circuit

2008-1352

TRIANTAFYLLOS TAFAS,

Plaintiff–Appellee,

and

SMITHKLINE BEECHAM CORPORATION (doing business as GlaxoSmithKline),
SMITHKLINE BEECHAM PLC, and
GLAXO GROUP LIMITED (doing business as GlaxoSmithKline),

Plaintiffs–Appellees,

v.

JOHN J. DOLL, Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office,
and UNITED STATES PATENT AND TRADEMARK OFFICE,

Defendants–Appellants.

Appeal from the United States District Court for the Eastern District of Virginia in consolidated case nos. 1:07-CV-846 and 1:07-CV-1008, Senior Judge James C. Cacheris.

RADER, Circuit Judge, concurring in part and dissenting in part.

I concur with this court's conclusion that the PTO is not entitled to Chevron deference with respect to its own rulemaking authority. However, in my view, the Final Rules are substantive, not procedural. Thus, I would affirm the district court's conclusion that the PTO exceeded its statutory rulemaking authority in promulgating these rules. For that reason, I concur in part with this court's ultimate conclusion regarding Final Rule 78, but dissent in part with respect to Final Rules 114, 75, and 265.

This case presents a threshold question about the nature of these rules—substantive or procedural. The organic act of the PTO "does NOT grant the Commissioner the authority to issue substantive rules." Merck & Co. v. Kessler, 80 F.3d 1543, 1550 (Fed. Cir. 1996) (emphasis in original). Unlike grants of rulemaking authority to many other administrative agencies, the PTO does not enjoy substantive rulemaking authority. Accordingly, the legislative branch has retained the responsibility for developing substantive patent law. To the extent that the PTO's Final Rules are substantive, this court cannot permit the PTO to exceed its authority.

The distinction between substantive or non-substantive rules requires a difficult judgment. This distinction arises most often in the context of interpreting the exception to the requirement for notice and comment procedures in the Administrative Procedure Act ("APA"). 5 U.S.C. § 553(b)(A). In the most common scenario, an agency has promulgated a rule without undergoing the strictures of notice and comment rulemaking. The reviewing court must then, when necessary, apply the APA's exemption for "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." Id. In other words, the courts may only sustain non-substantive rulemaking in those cases. See, e.g., Animal Legal Def. Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991); JEM Broad. Co. v. FCC, 22 F.3d 320 (D.C. Cir. 1994); Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037 (D.C. Cir. 1987). These cases have set forth a balancing test to identify a non-substantive rule: a rule is sufficiently non-substantive "where the policies promoted by public participation in rulemaking are outweighed by the countervailing considerations of effectiveness, efficiency, expedition and reduction in

expense." Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp., 589 F.2d 658, 662 (D.C. Cir. 1978).

The instant case, however, presents a different situation. These PTO rules have no procedural defects. Instead, this case asks this court to ensure that the PTO has not exceeded its rulemaking authority. Thus, in the present context, this court misapplies the teachings of cases such as Animal Legal Defense Fund and Cooper Technologies Co. v. Dudas, 536 F.3d 1330 (Fed. Cir. 2008). These cases focus on the distinction between "interpretative" and "substantive" rules. Parsing the difference between "interpretive," "procedural," and "policy" rules may be relevant in the context of categorizing a rule into one of the APA's exceptions to notice and comment rulemaking, but has no relevance to the question of exceeding a grant of rulemaking authority. In the unique context of this case, it makes no sense to classify a rule as "procedural" or "interpretative." Either of those labels leads to the same conclusion—that the rule is non-substantive. See Cooper Techs., 536 F.3d at 1336 (finding the PTO's interpretation of "original application" in 35 U.S.C. § 4608 to be "procedural" within the meaning of 35 U.S.C. § 2(b)(2) because it was "'interpretative' . . . rather than 'substantive'"); see also Animal Legal Def. Fund, 932 F.2d at 927 (contrasting "substantive" rules with the general category of "exempt 'interpretative' rules of section 553(b)"). Thus, I would not so casually discard, as this court does today, this court's precedent for identifying a "substantive" rule.

The Supreme Court provided valuable guidance on the substantive/non-substantive inquiry in Chrysler Corp. v. Brown, 441 U.S. 281 (1979). In Chrysler, the Court defined an inherent characteristic of a "substantive" or "legislative-type" rule,

namely, such rules "affect[ ] individual rights and obligations." Id. at 302. Contrary to this court's analysis today, the Chrysler Court's reasoning was in no way limited to defining the boundary between interpretative and substantive rules. The Court sought to draw a broad distinction between substantive and non-substantive rules—the same inquiry presented in this case. Id. Shedding light on this distinction, the Court recognized that "[a] 'substantive rule' is not defined in the APA," but that the term is best defined by "negative inference." Id. at 301-02 (emphasis added). Put differently, a rule is "substantive" if it is not an "interpretive rule[ ], general statement[ ] of policy, or rule[ ] of agency organization, procedure, or practice." Id. at 301.

Both this court and the Court of Appeals for the District of Columbia Circuit have relied on Chrysler in building a body of jurisprudence germane to the substantive/non-substantive inquiry. Central to this jurisprudence is the recognition that classifying a rule as substantive or non-substantive is a case-by-case exercise, poorly suited for bright-line rules. See, e.g., Bowen, 834 F.2d at 1045 ("Determining whether a given agency action is interpretive or legislative is an extraordinarily case-specific endeavor . . . . [A]nalogizing to prior cases is often of limited utility in light of the exceptional degree to which decisions in this doctrinal area turn on their precise facts."); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) ("[T]he question whether a rule is substantive or procedural for the purposes of § 553(b) is functional, not formal.").

No doubt, the Chrysler Court's inquiry—whether a rule "affects individual rights and obligations"—if analyzed in a vacuum, would blur the line between substantive and non-substantive rules. See, e.g., Bowen, 834 F.2d at 1046 ("[T]he mere fact that a rule

may have a substantial impact does not transform it into a legislative rule."); Neighborhood TV Co. v. FCC, 742 F.2d 629, 637 (D.C. Cir. 1984) ("[E]very change in rules will have some effect on those regulated.") (internal quotation marks omitted). For this reason, as the D.C. Circuit stated in JEM, the "critical feature" of a procedural, non-substantive rule is that "it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which the parties present themselves or their viewpoints to the agency." JEM, 22 F.3d at 326. Although the court's opinion today seizes upon this instructive language from JEM, it sadly overlooks JEM's ensuing statement: "[t]he issue, therefore, is one of degree . . . our task is to identify which substantive effects are sufficiently grave . . . ." Id. at 327 (emphases added) (internal quotation marks omitted). Assessing the challenged FCC rule's impact, which merely curtailed "a license applicant's right to a free shot at amending its application," the court in JEM concluded that the rule was "not so significant" as to be classified as substantive. Id. (emphasis added). Thus, as JEM illustrates, the test for substantive, ultra vires rules is a case-by-case inquiry, not a rigid application of a sentence out of context in JEM.

To my eyes, this question of degree must guide this court's assessment of the substantive nature of the PTO's Final Rules. This court has confronted that question before and gauged a rule's impact on parties' rights and obligations by examining the rules' changes to existing law or policy. See, e.g., Cooper Techs., 536 F.3d at 1336; Animal Legal Def. Fund, 932 F.2d at 927. The D.C. Circuit has also adopted this language as relevant to the inquiry. See, e.g., Bowen, 834 F.2d at 1045 ("Substantive rules are ones which grant rights, impose obligations, or produce other significant

effects on private interests, or which effect a change in existing law or policy.") (internal citations and quotation marks omitted). For example, in Cooper Technologies, this court held that a PTO rule giving effect to the term "original application" was non-substantive because it "does not effect any change in existing law or policy; rather, it is a prospective clarification of ambiguous statutory language regarding a matter of procedure." 536 F.3d at 1336. Similarly, in Bowen, a manual promulgated by the Department of Health and Human Services was a "classic procedural rule[]" because, in mapping out an enforcement strategy for third party contractors, it "impose[d] no new burdens on hospitals." Bowen, 834 F.2d at 1050-51.

The D.C. Circuit's 1999 decision in Chamber of Commerce is particularly instructive. 174 F.3d at 206. In that case, the court considered a new directive promulgated by the Occupational Safety and Health Administration ("OSHA") establishing a new compliance program for dangerous workplaces. Id. at 208. The Directive provided that the agency would reduce the probability of an onerous inspection if a workplace implemented a so-called comprehensive safety and health program ("CSHP"). Id. Although "[m]ost of the [CSHP] requirements are procedural," the Directive was clear that compliance with the Occupational Safety and Health Act was "not in itself sufficient" for compliance with the newly promulgated CSHP. Id. Plaintiffs challenged the Directive on the ground that it was a substantive rule, and OSHA had not undergone the requisite notice and comment procedures. Id. at 209. The court agreed with the plaintiffs, holding that the rule was substantive "[a]t least to the extent that participation in the CCP requires more than adherence to existing law . . . ." Id. at 211 (emphasis added). Indeed, because the Directive imposed upon

employers "more than the incidental inconveniences of complying with an enforcement scheme," it was plainly substantive. Id. at 211-12 (internal quotation marks omitted).

Implicit in the majority's holding that the Final Rules are procedural is that the rules fit within the "procedural" exception to the APA's notice and comment requirement. Yet applying this logic, the PTO would never be subject to the APA's notice and comment procedures because it only has statutory authority to promulgate rules that fall within exceptions to notice and comment, i.e., non-substantive rules. Here, the PTO provided a notice and comment period. In other words, the PTO recognized that "the policies promoted by public participation in rulemaking . . . outweigh[ed] . . . countervailing considerations of effectiveness, efficiency, expedition and reduction in expense." See Guardian Federal, 589 F.2d at 662 (providing that notice and comment is not required when these "countervailing considerations trump public participation"). The public participation during that period was overwhelming (itself an indication of the substantive impact of the rules?). Many of the comments shared a common concern: that the Final Rules "had a significant effect on private interests, and marked a change in existing law or policy." I share that concerned view.

II

Contrary to this court's holding today, the Final Rules are not "incidental inconveniences of complying with an enforcement scheme." The Final Rules are substantive. The Final Rules affect individual rights and obligations, and mark a startling change in existing law and patent policy. As the district court correctly noted,

> The 2+1 Rule and the 5/25 Rule, which limit continuing applications, RCEs, and claims, and the ESD requirement, which shifts the examination burden onto applicants, constitute a drastic departure from the terms of the Patent Act as they are presently understood. By so departing, the

> Final Rules effect changes in GSK's and Tafas's existing rights and obligations.

Tafas v. Dudas, 541 F. Supp. 2d 805, 814 (E.D. Va. 2008) (emphasis added). I will briefly consider each Final Rule in turn.

A. Final Rule 78

Final Rule 78 restricts to two the number of continuation applications entitled to an earlier priority date, unless the applicant files a petition showing that the amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application ("petition and showing"). As this court notes today, that rule contravenes the language of 35 U.S.C. § 120. The statute is clear: later filed continuation applications "shall have the same effect, as to such invention, as though filed on the date of the prior application." 35 U.S.C. § 120 (emphasis added). Final Rule 78 is not "a prospective clarification of ambiguous statutory language regarding a matter of procedure," Cooper Techs., 536 F.3d at 1336, because the statute mandates that continuations "shall have the same effect." Section 120 creates a substantive right to claim the earlier priority date in later-filed continuation applications.

In fact, this court's predecessor considered the language of 35 U.S.C. § 120: "[T]here is no statutory basis for fixing an arbitrary limit to the number of [continuing] applications" that can retain the benefit of the priority date. In re Henriksen, 399 F.2d 253, 254 (CCPA 1968). The court recognized that placing "a limit upon continuing applications is a matter of policy for the Congress." In re Hogan, 559 F.2d 595, 604 n.13 (CCPA 1977). In other words, Final Rule 78 attempts to usurp legislative prerogatives. If the Act contemplated a limit on the number of continuation applications

available as a matter of right, then a limitation to that effect would appear in § 120. Instead § 120 says the opposite.

The Office argues that Final Rule 78 is not substantive because the petition and showing requirement provides an alternative avenue for seeking additional continuations. The PTO's argument admits far too much. In order to receive the benefit of priority for later-filed continuation applications, which was previously available as a matter or right, the applicant must now justify the right with further showings. This new "petition and showing" hurdle is neither required nor contemplated by § 120. In mechanically applying only one statement from JEM, the majority opinion ignores that the "substantive effect" of failing to meet this new obligation—the loss of priority date—is "sufficiently grave" to make this rule substantive. See JEM, 22 F.3d at 327.

B. Final Rule 114

The same holds true with respect to Final Rule 114, imposing a limit of one request for continued examination ("RCE") per application family. The American Inventor's Protection Act of 1999 stated that the RCE provisions "shall apply to all applications" filed on or after June 8, 1995. The Act did not impose or contemplate a restrictive RCE practice. To the contrary, subject to the doctrine of prosecution laches, applicants could file an RCE as a matter of right.

The impact and reach of the Final Rules 78 and 114 ("the 2+1 Rule") significantly affects patent prosecution. Several amicus briefs point out reasonable scenarios where an applicant may choose to file an RCE during prosecution, e.g., in order to provoke an interference, to clarify claim scope in anticipation of litigation, and to submit an

information disclosure statement ("IDS"). Yet these Final Rules could interfere with those reasonable scenarios.

By way of example, consider the following scenario: An applicant receives a Notice of Allowance for application A. Before paying the issue fee, the applicant discovers a material prior art reference in a foreign application. Mindful of the duty to disclose material information to the Office, that applicant would file an RCE, an IDS citing the reference, and an amendment to account for the newly discovered prior art. So far so good, but what if the reference is not only material to application A, but also material to continuation applications B and C, members of the same application family that have also received Notices of Allowance? Under the 2+1 Rule, the applicant would have exhausted the two continuations and one RCE. What happens to applications B and C? Even if the submission of newly-discovered prior art satisfied the "petition and showing" requirement (which the PTO has said it will likely not), the "petition and showing" requirement is legislative because it imposes a new burden on the inventor. Because they require "more than adherence to existing law," Final Rules 78 and 114 are substantive. See Chamber of Commerce, 174 F.3d at 211.

C. Final Rule 75

Final Rule 75 limits an application to five independent claims or twenty-five claims total. Placing an arbitrary limit on the number of claims in an application drastically affects an applicant's rights and obligations under the Patent Act. To be specific, this rule alters obligations under 35 U.S.C. §§ 102, 103, 112, and 131. For instance, § 112, ¶ 2 requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the

applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (emphasis added). Placing a mechanical cap on the number of claims in an application hinders an applicant's right (and obligation) to "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention." Id. Indeed, "one or more claims" suggests at least one, not a ceiling to the number of claims in an application. Once again, if the Act wished to specify an upper limit on the number of claims, it could do so right at this point. Instead the "or more" requirement places no limit on the number of claims. The Act instead articulates a clear policy in favor of allowing as many claims as an applicant is willing to pay for.

As the majority opinion acknowledges, this court's precedent suggests no limit on the number of claims. See In re Wakefield, 422 F.2d 897, 900 (CCPA 1970) ("[A]n applicant should be allowed to determine the necessary number and scope of his claims . . . ."); In re Chandler, 319 F.2d 211, 225 (CCPA 1963) ("[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). This court should and does understand that some inventions are easier to describe, or lend themselves well to drawings. Others are more complicated and may take several iterations of claims in order to capture and fully disclose one's invention.

By analogy, this rule has a similar effect to imposing a five-page limit on applications. Although that notion is obviously too simplistic and problematic, this court's rationale would apparently make that hypothetical rule possible as a procedural

rule that merely "[alters] the manner in which the parties present themselves or their viewpoints to the agency." JEM, 22 F.3d at 326. To my eyes, much more is at stake.

Likewise, limiting an applicant to five independent claims ignores the varying scopes and methods of claiming inventions across different technologies. For example, in a pharmaceutical application, an applicant may claim not only the genus compound, but also a number of species, intermediates, methods of making, and methods of use. Asking an inventor to limit her application to five independent claims disproportionately affects technologies with greater complexity and greater public interest in disclosure. See Neighborhood TV, 742 F.2d at 637 ("In determining whether a rule is substantive, we must look at its effect on those interests ultimately at stake in the agency proceeding.").

This court today forgets that an inventor's incentive to disclose is commensurate with the protection available. With less ability to claim myriad methods of making, methods of use, species and intermediates, and more, an inventor will have less incentive to disclose the full dimension of the technological advance. Final Rule 75 frustrates the quid pro quo contemplated by the Patent Act.

D. Final Rule 265

On appeal, the PTO submits that limiting an application to five independent claims, or twenty-five claims total, is not a mechanical limitation, but just a trigger to the requirement to file an Examination Support Document ("ESD"). Final Rule 265 goes too far, however, by requiring an applicant to "conduct a broad search of patents, patent applications, and literature, and provide, among other things, a 'detailed explanation' of 'how each of the independent claims is patentable over the cited references.'" Tafas,

541 F. Supp. 2d at 816 (quoting 37 C.F.R. § 1.265(a)). Setting aside its onerous burden and its risk to cause later allegations of inequitable conduct, the ESD requirement improperly shifts the burden of proving patentability onto the applicant — a direct conflict with this court's interpretation of section 102.

Section 102 provides "[a] person shall be entitled to a patent unless" and section 131 provides that "[t]he director shall cause an examination to be made of the application." 35 U.S.C. §§ 102, 131. Thus, the PTO bears the burden of putting forth a prima facie case of unpatentability. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Indeed, this court has recognized that an applicant does not have the duty to perform a prior art search. Frazier v. Roessel Cine Photo Tech, Inc., 417 F.3d 1230, 1238 (Fed. Cir. 2005).

Although this court has upheld the PTO's authority to request "such information as may be reasonably necessary to properly examine or treat the matter," Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1282 (Fed. Cir. 2005), Rule 105 relates to information that is already in the applicants' possession; it does not impose an affirmative duty to perform a prior art search or opine regarding patentability over the closest reference. See 37 C.F.R. § 1.105. In contrast, the ESD requirement places a new obligation on the inventor. The ESD is something more than supplying the Office with an English language translation or turning over information already in the applicant's possession. It shifts the burden of proving patentability onto the applicant.

This shift of the burden of proof (or production, for that matter) onto the applicant significantly alters practice before the PTO and represents "a change in existing law or policy." Animal Legal Def. Fund, 932 F.2d at 927. Satisfaction of the ESD requirement

requires "more than adherence to existing law" and amounts to "more than the incidental inconveniences of complying with an enforcement scheme." See Chamber of Commerce, 174 F.3d at 211-12. As such, Final Rules 75 and 265 are substantive.

III

Because the Final Rules drastically change the existing law and alter an inventor's rights and obligations under the Patent Act, they are substantive and the PTO exceeded its statutory rulemaking authority under 35 U.S.C. § 2(b)(2). For the reasons stated above, I would affirm.

LEXSEE 535 F.2D 631

# IN THE MATTER OF THE APPLICATION OF MORRIS D. WILDING

**Patent Appeal No. 76-544**

**UNITED STATES COURT OF CUSTOMS AND PATENT APPEALS**

*535 F.2d 631; 1976 CCPA LEXIS 160; 190 U.S.P.Q. (BNA) 59*

**June 3, 1976, DECIDED.**

**PRIOR HISTORY:** [**1] Serial No. 642,208.

**OPINION BY:** LANE

## OPINION

[*632] LANE, Judge.

This is an appeal from the decision of the Patent and Trademark Office Board of Appeals (board) affirming the rejection of claims 1, 2, 5, 6, 8-15, 19, and 23-25 in application serial number 642,208, filed May 29, 1967, entitled "Soybean Granules." We reverse.

The Invention

Appellant's invention is a method for producing a protein food product having an expanded, elongated cellular structure similar to that of lean meat. Claim 1 adequately describes the method.

1. A method for preparing an improved protein food product comprising: forming a dough containing from about 15% to about 45% by weight, of water and defatted, undenatured, solventextracted oil seed protein material; heating said dough for a period of time less than about 5 minutes under pressure to a temperature of about 260 degrees F. to about 380 degrees F., sufficient to rapidly denature the protein of said dough, said dough having sufficient plasticity to be extruded in a self-binding form; and extruding said heated dough into an area of reduced pressure under conditions causing the dough to expand by the flashing of moisture therefrom, and causing [**2] sufficient denaturation to occur prior to said heated dough reaching said area so as to cause the product to retain an elongated cellular structure created by said flashing of moisture upon reaching said area.

Background

Appellant's application is a continuation-in-part of parent application serial number 436,358, filed March 1, 1965, which was involved in Interference No. 96,355 with Flier application serial number 600,471, filed December 9, 1966, and Atkinson application serial number 587,939, filed August 17, 1966. The count in issue in that interference read as follows:

The process of preparing an expanded food product which comprises mechanically working a protein mix of a solvent-extracted oil seed proteinaceous material having protein concentrations of at least 30 pet cent and water in a concentration of 15 to 60 percent, at a temperature above 200 degrees F. and under elevated pressure sufficient to convert said mix into a flowable substance, and extruding said flowable substance through an orifice into a medium of lower pressure.

Appellant was junior party in the interference by virtue of the fact that each of the other parties was accorded the benefit of an earlier [**3] filed application. 1 The Board of Patent Interferences awarded priority of invention of the subject matter involved to Flier. During the motion period in that interference appellant moved to dissolve the interference with respect to the count in issue and to add as an interference count the following:

1 Flier was accorded the benefit of application serial number 381,853, filed July 10, 1964. Atkinson was accorded the benefit of application serial number 369,189, filed May 21, 1964.

The process of preparing an expanded food product which comprises mechanically working a protein mix of a solvent-extracted oil seed proteinaceous material having protein concentrations of at least 30 percent and water in a concentration of at least 15 but not in excess of 60 [*633] percent, at a temperature above 200 degrees F and under elevated pressure sufficient to convert said mix into a flowable substance, and extruding said flowable substance through an orifice into a medium of lower pressure, in a manner to vaporize the moisture and expand the mixture to provide an expanded elongated fibrous cellular structure.

Appellant's motion was denied.

The Rejections

The examiner rejected [**4] all claims here on appeal under *35 USC 103* as unpatentable over the count of the interference "and the entire disclosure of Flier." [2]

2 The examiner apparently did not appreciate the fact that he could not reject appellant's claims under *35 USC 103* on the entire disclosure of Flier since the sole basis for using the disclosure of a winning party to an interference to reject the losing party's claims is interference estoppel. The disclosure cannot be used as "prior art" in a rejection under *35 USC 102* or *103*.Of course the lost count alone is available as prior art under *section 102(g)* and thus 103 to the extent that it represents the prior invention of another in this country. See *In re McKellin, 529 F.2d 1324, 188 USPQ 428 (CCPA 1976)*. It also should be noted that even under the doctrine of interference estoppel the entire disclosure of Flier could not be used as a basis for a rejection of appellant's claims, but only that portion of Flier's disclosure corresponding to the subject matter claimed which is clearly common to both appellant's and Flier's application. See *In re Risse, 54 CCPA 1495, 378 F.2d 948, 154 USPQ 1 (1967)* for a complete discussion of this issue.

The [**5] Board

The board noted the extensive differences between the claims on appeal and the lost count and concluded that the claimed method is neither anticipated by, nor obvious in view of, the process recited in the count. It therefore refused to sustain the rejection to the extent that it was based only on the interference count. [3] The board did, however, recognize that under some circumstances portions of the disclosure of a winning party to an interference could be used as a basis for rejecting claims in the application of the losing party. The board then noted disclosures which were common to both appellant and Flier regarding materials used and process conditions employed. In particular the board noted the use of identical or overlapping ranges in the respective applications for the oil content, moisture content, pH value, and protein content of the soybean meal, and for the temperatures and pressures employed in the process. The board also found that the descriptions of the end products were the same in both applications.

3 The board, in effect, found a patentable distinction between the claims on appeal and the count lost in the interference. See *In re Cole, 23 CCPA 1057, 1063, 82 F.2d 405, 409, 29 USPQ 137, 141 (1936).*

[**6] In reviewing the two disclosures, however, the board noted some distinctions:

The most notable distinction between the Flier disclosure and that of appellant is the absence of any description [in Flier] of the starting soybean meal as being undenatured, and that a denaturing occurs in the extruder prior to the extrusion of the material into the reduced pressure area (the ambient atmosphere). However, we do not believe that there is any substantive distinction between the process of Flier and that of the appellant. Nowhere in the body of the Flier application is there any indication that the soybean starting material has received any treatment other than grinding and a solvent extraction of the oil. Denaturing requires a chemical-physical treatment of the soybean in order to achieve denaturing. No such treatment is described, and the soybean meal is not disclosed as having undergone such a treatment. There is therefore no reasonable basis from the Flier disclosure for presuming that the soybean meal is not undenatured.

* * *

In our view, a fair reading of the Flier application, as

noted above, leads to the conclusion that undenatured soybean meal is employed as the material **[**7]** in the process there described. We are also of the view that the treatment which the **[*634]** soybean meal is subjected to in the Flier extruder under the conditions disclosed would necessarily result in a denaturing of the soybean meal prior to extrusion.

The board then concluded:

In view of the above discussion, we find that the claims on appeal read directly on the subject matter which is common to both the appellant's applications and the Flier application, and under such circumstances, the Examiner here properly rejected the claims as unpatentable over the Flier application. The appellant's motion during the interference proposed a count which differs from the present claim in substantially the same manner as did the original count. The appellant therefore cannot be considered to be in the position of a party who attempted to put into issue during the interference the subject matter now claimed, but was refused.The subject matter which is now claimed and common with that of Flier was never attempted to be put into the interference by the appellant.

OPINION

The first order of business is to note the confusion surrounding the rejection before us. Although the board **[**8]** stated that it reversed the examiner's rejection to the extent that it was based on using the count alone as "prior art" under *section 103* (via 102(g)), it failed to clearly indicate whether or not it affirmed the examiner's *section 103* rejection based on the entire disclosure of the Flier application.The board addressed itself to the subject matter which is commonly disclosed in appellant's application and that of Flier, implying to us that the board realized that the only possible rejection of appellant's claims on this record would have to be based on interference estoppel, a ground of rejection not specifically delineated by the examiner. However, the concluding paragraph of the board opinion states:

Accordingly, for the reasons given by the Examiner, particularly those emphasized above, the Examiner's decision is affirmed. [Our emphasis.]

After this opinion appellant petitioned for reconsideration, alleging, inter alia, that the board advanced a new ground of rejection in its opinion. In a second opinion the board responded to this allegation:

Contrary to the appellant's assertions, we did not advance any new grounds of rejection. We at most merely gave a slightly **[**9]** more expanded discussion than did the Examiner, but no new rejection was made by us.

The brief of the solicitor never once argues the propriety of the examiner's rejection under *section 103*. Rather, the entire brief concentrates on the propriety of the rejection of appellant's claims based on interference estoppel.

Because we find that no matter which ground of rejection is before us, the board must be reversed, we will not speculate about what the board did or did not do in its opinion regarding the examiner's original rejection. [4]

> 4 This is not to say that we condone the actions of the PTO in not making clear to appellant the grounds for rejecting his claims.

Since our decision in *In re Risse, 54 CCPA 1495, 378 F.2d 948, 154 USPQ 1 (1967)*, the law has been settled that a rejection of a losing party's claims under *35 USC 103* using the entire disclosure of the winning party is improper. We repeat what we said in Risse:

We see no reasonable basis for a contention that an award or concession of priority necessarily makes the complete disclosure of the winning party's application available as prior art, either by itself or in combination with other art, against the **[**10]** losing party's application. [*Id. at 1503, 378 F.2d at 954, 154 USPQ at 6* (emphasis in original).]

We noted in that opinion the confusion which had been prevalent between the concept of interference estoppel and prior art under *sections 102* and *103* and stated:

**[*635]** The distinction which should be borne in mind is that, with regard to interference estoppel, the losing party is only estopped to obtain claims which read directly on disclosures of subject matter clearly common to both the winning party's application and that of the losing party; but that, with regard to prior art (including prior invention), the losing party cannot obtain claims to subject matter which is either barred under *35 USC 102(g)*, or rendered obvious under *35 USC 103*, by the

invention defined in the interference counts. [*Id. at 1506, 378 F.2d at 957, 154 USPQ at 8* (emphasis in original).]

Therefore, to the extent the board may have affirmed the examiner's rejection of appellant's claims under *35 USC 103*, using the entire Flier disclosure, that decision must be reversed.

As noted above, we did recognize in Risse that under appropriate circumstances portions of a winning party's disclosure may **[**11]** be used as a basis for rejecting a losing party's claims under a theory of interference estoppel. However, for the doctrine of interference estoppel to apply, the PTO must show that appellant's claims read on disclosures which are clearly common to both the winning party's application and that of the losing party. Since the rationale for the doctrine of interference estoppel is that priority with respect to the claimed invention could have been determined in the interference, a showing of common subject matter must of necessity include a showing that Flier had support for the invention as claimed. As proponent of the rejection the PTO has the burden of showing that the use of undenatured soybean meal is inherent in the Flier application.

The board acknowledged that Flier does not contain an express disclosure of the use of an undenatured [5] soybean meal as a starting material in the claimed process. Similarly, the board acknowledged that Flier contains no express disclosure that denaturation occurs during the heating step of the disclosed process. It pointed out, however, that there is no reasonable basis from a reading of the Flier disclosure for presuming that Flier's soybean **[**12]** meal is not undenatured, particularly since there are no disclosed preprocessing operations on the soybean which might denature it.

> 5 The following definition of denature has been provided in the solicitor's brief and was taken from Webster's Third New International Dictionary (1961):
>
> 2: to so modify (a native protein) esp. by heat, acid, alkali or ultra-violet radiation that some of the original properties (as solubility and specific activity) no longer are present or present in the same degree owing to a change in molecular structure.

We do not believe that this is enough to show inherency, particularly in view of appellant's evidence tending to negate any inherency. We first note an affidavit by Hale submitted during prosecution [6] of Flier's application in which it was stated that the Flier process embodied in his application was used to make Chuck Wagon [7] dog food. Another amendment [8] submitted during prosecution of the Flier application, stated that the red chunk of Chuck Wagon dog food was made by the Flier process. In separate litigation [9] involving the alleged infringement of *Patent No. 3,047,395* by the method of making the red chunks in the Chuck Wagon **[**13]** product, the assignee of the Flier application represented to the court that the red chunks of the Chuck Wagon product were made from denatured soybean material. In a memorandum written by the court in that litigation reference is made to the use of denatured soybean meal in the process producing the red chunks in the Chuck Wagon product:

> 6 Submitted in an amendment filed April 10, 1968.
>
> 7 Registered trademark of Ralston Purina Company. Ralston Purina is also the assignee of the Flier application.
>
> 8 Submitted July 13, 1972.
>
> 9 Ralston Purina Co. v. General Foods Corp., No. 67 C 413(2) (E.D. Mo. Sept. 9, 1969).

The Ralston [Flier] process starts with soybean meal which has been toasted and is almost complete denatured.

* * *

**[*636]** The toasting process consists of steaming, heating, flaking the beans, removing the oil and fat from them and then drying and grinding. This process has been used at Ralston since 1959. The toasting process results in almost completely denaturing the starting material.

That memorandum also details many of the process steps used to make the red chunks which correspond to the process steps disclosed in the Flier application. **[**14]** Although this evidence does not conclusively prove that the soybean meal utilized in the Flier application must be denatured, it is sufficient to indicate that the use of denatured soybean meal in the Flier application is not the necessary and only reasonable construction to be given the Flier disclosure. *In re Filstrup, 45 CCPA 783, 251 F.2d 850, 116 USPQ 440 (1958)*. The use of a preprocessing toasting procedure in which denaturation occurs is entirely consistent with the

Flier disclosure. For the doctrine of inherency to apply it must be inevitable that Flier uses an undenatured soybean meal. *Pingree v. Hull, 518 F.2d 624, 186 USPQ 248 (CCPA 1975).*

Since the PTO has failed to show that the use of undenatured starting material is inherent in Flier, it has failed to demonstrate that the claimed subject matter is clearly common to both appellant's application and that of Flier.

In view of the fact that we have not found the subject matter of the appealed claims to be common to both applications, we have no need to consider appellant's arguments that interference estoppel should not apply because of his attempt to add the proposed count in the interference.

Accordingly, the **[**15]** decision of the board is reversed.

REVERSED

LEXSEE 789 F.2D 1574

**IN re LEONARD KAPLAN and WELLINGTON EPLER WALKER**

**No. 85-2522**

**UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT**

***789 F.2d 1574*; *1986 U.S. App. LEXIS 21209*; *229 U.S.P.Q. (BNA) 678***

**May 6, 1986**

**PRIOR HISTORY:** **[**1]** Appealed from: U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

**COUNSEL:** Steven T. Trinker; of Danbury, Connecticut, Argued, for Appellant. On the brief was Norman L. Balmer, Law Department, Union Carbide Corp., of Danbury, Connecticut.

Harris A. Pitlick, Associate Solicitor, of Arlington, Virginia, Argued, for Appellee U.S. Patent and Trademark Office. With him on the brief were Joseph F. Nakamura, Solicitor and Fred E. McKelvey, Deputy Solicitor.

**JUDGES:** Rich, Circuit Judge, Nichols, Senior Circuit Judge, and Nies, Circuit Judge.

**OPINION BY:** RICH

**OPINION**

**[*1574]** RICH, Circuit Judge.

This appeal is from the decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) rejecting, under 37 CFR 1.196(b), the single claim of appellants' application serial No. 364,221, filed April 1, 1982, entitled "Homogeneous Liquid Phase Process for Making Alkane Polyols," on the sole ground of "double patenting, because it constitutes an improper extension of monopoly for an invention claimed by Kaplan." We reverse.

*Background*

The Kaplan and Walker application at bar and the cited Kaplan patent, No. 3,944,588, **[**2]** issued Mar. 16, 1976, to one of the appellants on an application filed Jan. 2, 1975, are both assigned to Union Carbide Corporation, the real party in interest. As is apparent, the Kaplan patent application was pending only about fourteen and a half months. It was copending with the great-great-grandparent of the application at bar, filed Sept. 30, 1975. Its title is "Catalytic Process for Polyhydric Alcohols and Derivatives." The Kaplan patent contains one independent claim and thirteen dependent **[*1575]** claims. The claims most relevant here are those incorporated in dependent claim 4, which is the only claim specifically relied on by the board to support its double patenting rejection. They read as follows (emphasis ours):

> 1. The process of making alkane diols and triols having from 2 to 3 carbon atoms in the molecule which comprises reacting in a homogeneous liquid phase mixture of hydrogen and oxides of carbon in the presence of a rhodium carbonyl complex and a trialkanolamine borate at a pressure of from about 1000 psia to about 50,000 psia correlated with a temperature of about 100 degrees C to about 375 degrees C sufficient to produce said diols and triols. **[**3]**
>
> 2. The process of *claim 1* wherein the temperature is from about 150 degrees C

to about 300 degrees C.

4. The process of *claim 2* wherein the reaction is effected *in the presence of an organic solvent*.

Among organic solvents disclosed and specifically claimed in the Kaplan patent are two known as "tetraglyme" (in more explicit nomenclature, dimethyl ether of tetraethylene glycol) and sulfolane. Two of the Kaplan dependent claims (10 and 11) individually name these specific solvents, respectively. No claim in Kaplan calls for a solvent *mixture*, which is significant with respect to the double patenting rejection for reasons which will appear. There are, however, a number of *examples* of mixed solvents in Table VI of the Kaplan patent specification, particularly Example 45, upon which the board relied. Example 45 is specific to a mixture of "Tetraglyme/sulfolane (65/10)." The heading of Table VI is "Triisopropanolamine Borate in Mixed Solvents."

Against this much of the background, we now reproduce the single claim on appeal of this *joint* application of Kaplan and Walker which stands rejected for double patenting in view of claim 4 of the Kaplan [**4] patent (emphasis ours):

> *In the* homogeneous liquid phase *process* of producing alkane polyols by the reaction of oxides of carbon and hydrogen in the presence of a rhodium catalyst in which rhodium is complexed with carbon monoxide to provide a rhodium carbonyl complex at a temperature between about 100 degrees C. to about 375 degrees C. and a pressure between about 1000 psia to about 50,000 psia, *the improvement* which comprises effecting said reaction *in a solvent mixture of tetraglyme and sulfolane* under conditions whereby such solvent mixture is essentially inert and the *rate of formation of such alkane polyol is greater* than would be obtained by effecting said reaction under equal conditions using *tetraglyme or sulfolane* as the solvent.

It will be observed from a comparison of this claim with the Kaplan claims reproduced above that the Kaplan and Walker (joint) claim at bar is, generally speaking, defined as an improvement on the Kaplan (sole) catalytic process of producing alkane polyols (diols and triols) by reacting hydrogen and carbon oxides (e.g., carbon monoxide) in an organic solvent. The reason why the process using the solvent *mixture* [**5] of the appealed claim was not *claimed* in the Kaplan patent, although it is *disclosed* in the patent specification, is that Kaplan alone was not the inventor of that process; it was the *joint* invention of Kaplan and Walker and therefore the application on appeal was filed. The reason it was *disclosed* in Kaplan's patent was that it was part of the "best mode" of practicing Kaplan's catalytic process. *See 35 USC § 112*, first paragraph. ("The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention.") By the time Kaplan filed his application he knew of ("contemplated") the Kaplan and Walker improvement on his own sole invention and therefore he disclosed it. It is a given, of course, that a sole inventor and joint inventors including the sole inventor are separate "legal entities," a legal proposition from which certain legal consequences flow, *In re Land and Rogers, 54 C.C.P.A. 806, 368 F.2d 866, 879, 151 U.S.P.Q. (BNA) 621, 633 (CCPA 1966)*, [1] "such as who must [*1576] apply [**6] for patent." It is worth remembering an axiomatic statement on the same page of the *Land and Rogers* case, which is also applicable here:

> When the joint and sole inventions are related, as they are here, inventor A commonly discloses the invention of A & B in the course of describing his sole invention and when he so describes the *invention* of A & B he is not disclosing "prior art" to the A & B invention, even if he has legal status as "another." [the reference to "another" is to that word as used in *35 USC 102(e)* and *(g)*.]

1 All applications involved in this case were filed and the Kaplan patent had issued before amendment of *35 USC § 116* by P.L. 98-622 of Nov. 8, 1984, sec. 104(a), 98 Stat. 3384, now paragraph one of *35 USC § 116*, which reads:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and

> each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

The first sentence is the substance of the law at the times involved in this case. The second sentence is the liberalization added by the 1984 amendment, which, had it been available, might have obviated the problem in this case.

[**7] Having been filed during the pendency of the Kaplan application, the present Kaplan and Walker application with its single mixture claim had a difficult time in the PTO resulting in the passage of much time. To summarize, there were two appeals to the board prior to the appeal which resulted in the decision now before us. Three continuation applications were filed under *37 CFR 1.60*. The last of these, filed Jan. 9, 1981, is the present application and was appealed to the board from the examiner's rejections under *§§ 102(g)*, *102(a)*, and *103* based on the Kaplan patent and a patent to Pruett. Declarations under *37 CFR 1.131* were filed by appellants and by Kaplan explaining who invented what and when.

The board reversed all of the examiner's grounds of rejection and entered its own rejection on the ground of double patenting, as stated in the first paragraph hereof, which rejection was adhered to on reconsideration. Applicants sought reconsideration by the board "rather than reopening prosecution as is permitted under 37 C.F.R. 1.196(b)." Appellants then took this appeal. Therefore, this is the first review of the board's new rejection, explicated in its two opinions.

To [**8] indicate the reasoning of the board, we quote most of the paragraph of its initial opinion in which it made its new rejection (all emphasis ours):

> Under the provisions of 37 CFR 1.196(b), we reject claim 1 [there is no other] on the ground of double patenting, because it constitutes *an improper extension of monopoly* for [sic, of] an invention claimed by Kaplan. . . . At least claim 4 of the Kaplan patent and appellant's claim 4 of the Kaplan patent and appellant's claim 1 *embrace* common subject matter. Both claims are generic [2] and both claims *would be infringed* by a process which utilized rhodium and trialkanolamine borate as the catalyst and a *mixed solvent* as the organic solvent. Example 45 of the Kaplan patent clearly shows that the term solvent, as used in Kaplan's claims is intended to *embrace* the mixed solvent of Example 45. Further, appellants' claim 1 is sufficiently broad to *encompass* the use of a trialkanolamine borate in conjunction with the rhodium catalyst. Because both claims *embrace the same subject matter*, allowance of the instant application would amount to "double patenting of the improper extension of monopoly type" * as [**9] termed by Judge Almond in *In re Thorington, 57 C.C.P.A. 759, 769, 418 F.2d 528, 537, 163 U.S.P.Q. (BNA) 644, 650 (CCPA 1969)*.
>
> * We prefer the term "improper extension of monopoly" rather than "obviousness type double patenting" because the improper extension of monopoly occurs as a result of the *same* **[*1577]** *subject matter being claimed*. The rejected claims [sic] before us may well be drafted so broadly as to also embrace subject matter which is unobvious over the Kaplan patent. Nevertheless, for all practical purposes, the rejected claims [sic] serve to extend the monopoly for that subject matter *embraced* by the claims which is the same as that falling within the *embrace* of the Kaplan claims.
>
> 2 Just what the board meant by saying "both claims are generic" is not clear to us. The claims speak for themselves. Kaplan's claim 4 defines the solvent used in the

process, which is the limitation under discussion by the board, as "an organic solvent." Appellants' claim on appeal defines the solvent as "a solvent mixture of tetraglyme and sulfolane." Far from being "generic," the latter looks very much like a quite specific species of the genus "organic solvent."

[**10]

The board then discussed *In re Vogel, 57 C.C.P.A. 920, 422 F.2d 438, 164 U.S.P.Q. (BNA) 619 (CCPA 1970)*, a case on which appellants as well as the PTO rely before us, and continued:

> Accordingly, the instant claim, which reads on subject matter disclosed in and *embraced* by the claims of the Kaplan patent, cannot be granted absent filing of a *terminal disclaimer* to prevent undue timewise extension of monopoly.

The imposition of the terminal disclaimer originated with the board in conjunction with its origination of the double patenting rejection. From the dates set forth above, it will be seen that its effect would be to cause any patent issuing on the application at bar to expire on March 16, 1993, the expiration date of the Kaplan patent, assuming a term of 17 years, so that it would have a term of less than 7 years. Appellants have refused that option. And, of course, if the board's claim analysis is correct, appellants would gain little or nothing from the patent because the invention of the appealed claim, using the mixed solvents, is already *covered* by the Kaplan patent until the date of its expiration.

Following the filing [**11] of what the board characterized as "appellants' well-drafted Request for Reconsideration," of some 20 pages, the board wrote its second opinion, discussing further *In re Vogel* and some other CCPA double patenting opinions, emphasizing the following:

> The Kaplan patent deliberately chose to claim the use of organic solvents as a vehicle for carrying out the claimed process. . . . The Kaplan patent discloses numerous solvents . . . five of which are solvent mixtures and one of which is the tetraglyme/sulfolane solvent mixture which is claimed by appellant as the essential feature of their process. Surely, the tetraglyme/sulfolane solvent of Table VI *provides some of the support* for the term "organic solvent" as used in claim 4 of the Kaplan patent. [Emphasis ours.]
>
> . . .
>
> As indicated by the patent, the term "solvent" includes the same mixed solvent claimed by appellants. Being in some aspects the same, the subject of appellants' claims [sic] would have been *prima facie* obvious from the subject matter of the claims in the Kaplan patent. Appellants' evidence of unexpected results teaches no more than that which is disclosed in the patent and which is properly [**12] considered supportive of the claims

[sic], i.e., that mixed solvents give superior yields. Appellants' evidence does not overcome the *prima facie* case and a "terminal disclaimer" is necessary. . . .

OPINION

*Double Patenting Generally*

We reverse the board's double patenting rejection essentially for two reasons: (1) It has confused double patenting with "domination" which, by itself, does not give rise to "double patenting" and (2) it has used the disclosure of appellants' joint invention in the Kaplan patent specification as though it were prior art, which it is not, to support the obviousness aspect of the rejection.

By domination we refer, in accordance with established patent law terminology, to that phenomenon, which grows out of the fact that patents have claims, whereunder one patent has a broad or "generic" claim which "reads on" an invention defined by a narrower or more specific claim in another patent, the former "dominating" the latter because the more narrowly **[**13]** claimed invention cannot be practiced without infringing the broader claim. To use the words of which the board seemed to be enamored, the broader claim "embraces" or "encompasses" the subject matter defined by the narrower claim. In possibly simpler terms, one patent dominates another if a claim of the first patent reads on a device built or process practiced according to the second patent disclosure. This commonplace [*1578] situation is not, per se, double patenting as the board seemed to think. *In re Sarett, 51 C.C.P.A. 1180, 327 F.2d 1005, 1014, 1015, 140 U.S.P.Q. (BNA) 474, 482, 483 (CCPA 1964)*. (See particularly the quotations from E. Stringham's *Double Patenting* (1933) about terms such as "covered" and "embraced.")

With respect to the board's concern about "extension of monopoly," the PTO Solicitor's brief, while supporting the board, properly deplores its use of the ambiguous word "monopoly," preferring to use the more accurate and less emotion-generating expression [3] "extension of patent rights," explaining this in a footnote reading:

> Both the board in this case and some prior decisions of the CCPA use the term "monopoly" in referring **[**14]** to the rights obtained through the grant of a patent. We prefer to refer to "patent rights" based on the rationale given by Chief Judge Markey in his article "Why Not the Statute?," 65 J. Pat. Off. Soc'y 331, 331-333 (1983).

*See also Carl Schenck, A.G. v. Nortron Corp., 713 F.2d 782, 218 U.S.P.Q. (BNA) 698, n.3 (Fed. Cir. 1983)*; *Kayton on Patents*, 2d ed., 1-27, "E. Patents: Property Versus Monopoly." *Compare, Robinson on Patents* (1890) Chapt. II §§ 11-44.

> 3 The difficulty is that "monopoly" is used in different senses in patent and antitrust law, hence its ambiguity. Because of its antitrust connotations and association with illegality in connection therewith, it often evokes negative reactions inappropriate to a dispassionate analysis of patent law problems. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1367, 220 U.S.P.Q. (BNA) 763, 776 (Fed. Cir. 1984).*

More to the point of the board's concern, however, one must **[**15]** inquire more closely than did the board: extension of what patent right? Any patent granted on the application at bar will have the single claim on appeal which is expressly limited to carrying out the Kaplan process using the specific solvent *mixture* of tetraglyme *and* sulfolane invented by appellants. Is this an extension of a patent on Kaplan's invention -- Kaplan who never conceived of using that mixture? When Kaplan's (sole) patent expires, and assuming appellants get their joint patent, the world will still be free to use (so far as these two patents go) the Kaplan process so long as appellants' solvent mixture is not used in it. Of course, it may be that everyone will want to use the improvement, but that is commonly the case when dominating patents expire with improvement patents still outstanding.

In further clarification of the distinction between domination and double patenting as currently understood, we repeat a passage from E. Stringham's *Double Patenting* at 207, previously quoted in *Sarett*:

> One of the simplest, clearest, soundest and most essential principles of patent law, is that a later invention may be validly patented, altho [sic] dominated [**16] by an earlier patent, whether to the same or to a different inventor. No one will seriously deny the correctness of this statement, in principle. But it is incessantly lost sight of when an actual case must be decided.

"May be validly patented" of course implies that the "later invention" at least complies with the requirements for patentability found in the statute, namely, novelty, utility, and unobviousness as established by evidence of prior art, which a description of the later invention is not. Domination is an irrelevant fact.

The development of the modern understanding of "double patenting" began in the Court of Customs and Patent Appeals (CCPA) about the time of *In re Zickendraht, 50 C.C.P.A. 1529, 319 F.2d 225, 138 U.S.P.Q. (BNA) 22 (CCPA 1963)*, a rather unusual case in that there was no majority opinion because only two judges joined each of the two principal opinions. Neither *opinion* therein, therefore, can be regarded as controlling precedent in this court. That case is noteworthy primarily for the suggestion in a concurring opinion that the appellant might have disposed of the rejection by filing a terminal disclaimer under *35 USC § 253*. **[**17]** This suggestion precipitated a steady stream of appeals over the next few years dealing with double patenting and the effectiveness or otherwise of terminal disclaimers which resulted in revisions of the PTO's rules, [*1579] guidelines, and Manual of Patent Examining Procedure on the matter. By the time of *In re Vogel*, 1970, the court saw fit to make a restatement of the law of double patenting which serves as a good starting place for deciding this case.

The first question treated in the *Vogel* restatement is whether the *same invention* is being claimed twice. If so, *Vogel* states, *35 USC § 101* prevents two patents from issuing. *In re Boylan, 55 C.C.P.A. 1041, 392 F.2d 1017, 157 U.S.P.Q. (BNA) 370 (CCPA 1968)*. We need not linger over this question as that is not the rejection made by the board here, notwithstanding what it said about what the claims "embrace." [4]

4 For the latest decision of this court on the "same invention"

double patenting issue see *Studiengesellschaft Kohle mb H v. Northern Petrochemical Co., 784 F.2d 351, 228 U.S.P.Q. (BNA) 837 (Fed. Cir. 1986)*, a case in which it was expressly held that "obviousness-type double patenting is not involved in this case." The opinion may be of interest, however, for what it has to say about "domination" and delay in the issuance of a second patent due to proceedings in the PTO. F.2d at , 228 U.S.P.Q. at 841.

[**18]

The second question, says *Vogel*, is: "Does any claim in the application define merely an obvious variation of an invention disclosed and claimed in the patent? In considering the question, the patent disclosure may not be used as prior art. *In re Boylan, supra*; *In re Aldrich, 55 C.C.P.A. 1431, 398 F.2d 855, 158 U.S.P.Q. (BNA) 311 (CCPA 1968)*." The opinion went on to describe, and resolve, some of the logical difficulties in reaching a decision on whether there is or is not what has come to be known consistently as "obviousness-type double patenting," the ground of rejection now before us.

Should there be any doubt about the true ground of rejection before us in view of the board's stated preference for the term "improper extension of monopoly" instead of "obviousness-type double patenting," we observe that the brief of the PTO Solicitor states the issue to be whether the board was correct in rejecting the claim "on the ground of double patenting of the obviousness type." In the summary of argument is the statement: "Claim 4 [of Kaplan] and its [**19] supporting disclosure render the subject matter of the appealed claim obvious." In the argument proper, the brief says the main disagreement between appellants and the board "appears to be the interpretation of the so-called 'second analysis question' discussed in *In re Vogel*," and that is the obviousness-type double patenting question, which we quoted above.

We will say a word about the board's desire to depart from the established terminology in the law of double patenting for the reason, quoted earlier, that "the improper extension of monopoly [i.e., of the patent right] occurs as a result of the same subject matter being claimed." The board's first opinion said it was adopting terminology from Judge Almond's opinion in *Thorington*, another CCPA case in which the court undertook to restate the law of double patenting. Reading Judge Almond's opinion will show that it recognizes two types of double patenting: same invention type and obviousness type, the main significance of the distinction being that filing a terminal disclaimer is permitted to cure an obviousness type situation but not a same invention type situation. (The fact that the board here demanded a terminal [**20] disclaimer as a condition for allowance of the claim is another indication of the true nature of its rejection.) It is also clear from Judge Almond's opinion that he was using "extension of monopoly type" as synonymous with obviousness type, merely as a way of distinguishing from same invention type double patenting.

The main reason why one cannot use "extension of monopoly" *as a type designation*, however, is that it cannot serve that purpose because the basis for *both* same invention and obviousness-type double patenting rejections is timewise extension of the patent right. All proper double patenting rejections, of either type, rest on the fact that a patent has been *issued* and later issuance of a second patent will continue protection, beyond the date of expiration [*1580] of the first patent, of the very same invention claimed therein (same invention type double patenting) or of a mere variation of that invention which would have been obvious

to those of ordinary skill in the relevant art (obviousness-type double patenting). In the latter case, there must be some clear [**21] evidence to establish why the variation would have been obvious which can properly qualify as "prior art." Even if obviousness of the variation is predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was.

*Obvious Variation of what Kaplan Claims*

We turn now to consideration of the obviousness aspect of this obviousness-type double patenting rejection, which had to be based, of course, on what is *claimed* in the Kaplan patent. The board relied on Kaplan claim 4, which depends from claim 2, which depends from claim 1. These claims are set forth above. The board relied on the fact that claim 4 calls for "an organic solvent." The board did not say that the use of appellants' "solvent mixture of tetraglyme and sulfolane" would be obvious from claim 4. Indeed, in that portion of the board's opinion in which it reversed all of the examiner's rejections, the board held, on the record which contains appellants' declarations, that they, not Kaplan, invented the use of those mixed solvents, that appellants had antedated Kaplan as a reference under *35 USC § 102(e)*, that the Kaplan patent cannot be used to [**22] show obviousness under *§ 103*, and that appellants' claim was not obvious from a cited patent to Pruett et al. It also reversed a rejection under *§§ 102(g)*/103 for obviousness which used Kaplan as the sole basis. Then it turned about and made an obviousness-type double patenting rejection based on Kaplan's claim 4. This rejection was predicated on the novel argument, particularly set out in the board's second opinion on rehearing, that Example 45 in Kaplan (which is *appellants' invention*, disclosed in Kaplan's patent to conform with the best mode requirement of *§ 112*) "provides some of the support for the term 'organic solvent' as used in claim 4 of the Kaplan patent."

Thus, after concluding that the Kaplan patent is not available to show obviousness of appellants' claimed process, the board has nevertheless used Kaplan to show obviousness in a double patenting context, for it relied on no other reference. Moreover, that part of the Kaplan disclosure used to do this is a description of appellants' joint invention. The board's claim-support theory does not suffice to justify this anomalous result. There is adequate support for the "organic solvent" limitation in claim 4 [**23] apart from appellants' specific *mixed* solvent invention, including the disclosure of the separate solvents in the mixture which are separately claimed by Kaplan. There is no way the board could have found appellants' claimed invention to be an obvious variation of what Kaplan claims except by treating the Kaplan patent disclosure as though it were prior art. This has repeatedly been held in our precedents to be impermissible. *In re Vogel; In re Aldrich; In re Boylan*, all supra. In effect, what the board did was to use a disclosure of appellants' own joint invention which had been incorporated in the Kaplan sole disclosure to show that their invention was but an obvious variation of Kaplan's claimed invention. That amounts to using an applicant's invention disclosure, which is not a 1-year time bar, as prior art against him. That is impermissible. D. *Chisum, Patents § 3.08[2], § 5.03[3][f].*

The PTO brief argues that *Vogel* sanctions such use of Kaplan's disclosure. We disagree. We do not find the factual situation here comparable to that in *Vogel*; neither was the reasoning of the board underlying the *Vogel* rejection comparable to the claim-supporting [**24] theory of the board in this case. Each double

patenting rejection has to be decided on its own facts. *Vogel* dealt **[*1581]** with one difficult-to-analyze situation, this case presents a different one.

*Summary*

The double patenting rejection of appellants' single claim is *reversed* because the same invention is not being claimed, and because there is no proper evidence to show that the claim is for a mere obvious variation of what is claimed in the Kaplan patent relied on to support the rejection. There being no double patenting, the requirement for a terminal disclaimer was improper.

REVERSED

LEXSEE 327 F.2D 1005

**IN RE SARETT**

**No. 7051**

**United States Court of Customs and Patent Appeals**

***51 C.C.P.A. 1180*; *327 F.2d 1005*; *1964 CCPA LEXIS 475*; *140 U.S.P.Q. (BNA) 474***

**Oral argument December 2, 1963**
**February 20, 1964**

**PRIOR HISTORY:** [***1] APPEAL from Patent Office, Serial No. 600,163

**DISPOSITION:** Reversed.

**COUNSEL:** *Rudolph J. Anderson Jr., Merck & Co., Inc., I. Louis Wolk, Raymond J. McElhannon* and *Henry T. Burke,* for appellant.

*Clarence W. Moore (Raymond E. Martin,* of counsel) for the Commissioner of Patents.

**OPINION BY:** RICH

**OPINION**

[**1005] [*1182] Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Jr., Associate Judges

RICH, Judge, delivered the opinion of the court:

This appeal is from the decision of the Patent Office Board of Appeals, affirming the rejection of claims 8-19 in Saretts application serial No. 600,163, filed July 26, 1956, entitled "Chemical Compounds and Process for Preparing the Same." [1]

1 This application is a continuation-in-part of application serial No. 263,016 and 292,985, filed December 22, 1951, and June 11, 1952, respectively.

December 22, 1951, is also the filing date of the parent application serial No. 263,015 of the application which resulted in the Arth et al. *Patent No. 2,722,532* issued to the assignee of the present application, which patent is the only reference now relied on in rejecting the appealed claims.

The invention relates to the [***2] oxidizing of primary and secondary alcohols to corresponding carbonyl compounds. In essence, mild oxidizing agents are used, [**1006] thus preventing oxidation of unsaturated bonds in the alcohol and also preventing oxidation beyond the desired stage. Alkaline medium is used to avoid undesirable side reactions at acid-sensitive portions of alcohol molecules.

With respect to the naming of the alcohols to be oxidized, there are two groups of claims: (1) claims 8-14 which define the process of oxidizing specific complex alcohols using "pyridine-chromium trioxide [*1183] complex" as oxidizing agent; and (2) claims 15-19 which define the process of so oxidizing primary and secondary alcohols broadly. In this group the oxidizing agent is defined as in group (1) except for claim 15 in which it is more broadly defined as "a tertiary amine-chromium trioxide complex," pyridine being a tertiary amine, the tertiary amines being further restricted to "pyridine, lower alkyl substituted pyridines, and benzosubsituted pyridines." Claims 17-19, dependent on claim 16, specify, respectively, that the alcohol is aliphatic, or a phenanthrene compound, or a cyclopentanopolyhydrophenanthrene [***3] compound.

Claims 8 and 16 are representative of groups (1) and

(2) respectively and read (our emphasis):

> 8. A process for preparing 3-acetoxy-11,20-diketopregnane which comprises intimately contacting 3-acetoxy-11-keto-20-hydroxypregnane with pyridine chrominum trioxide complex at a pH in excess of 7.0 and recovering 3-acetoxy-11,20-diketopregnane from the resulting reaction mixture.
>
> 16. In the process of oxidizing an alcohol having at least one hydrogen atom attached to the carbon atom bearing the hydroxyl substituent to the corresponding carbonyl compound, the improvement which comprises intimately contacting said alcohol at a pH in excess of 7 with a pyridine-chromium trioxide complex, and recovering the carbonyl compound from the resulting reaction mixture.

The definition of the alcohol in claim 16 means, in plain English (the use of which is often prevented by Patent Office practice), a primary or secondary alcohol.

There are two grounds of rejection: (1) all claims, double patenting over Arth et al., a commonly-assigned patent in which appellant is one co-inventor; [2] and (2) claims 15-19, indefiniteness in their broad definitions of the alcohols, under *35 U.S.C.* **[***4]** *112.* [3]

2 *Patent No. 2,722,532*, issued Nov. 1, 1955, to Glen E. Arth, George I. Poos, and Lewis H. Sarett (the applicant herein), assignors to Merck & Co., Inc., Rahway, N.J. This patent issued on application serial No. 293,672, filed June 14, 1952, as a continuation-in-part of serial No. 263,015, filed December 22, 1951.

3 The board allowed one claim defining the process of oxidizing n-butyl alcohol to n-butyraldehyde with pyridine-chromium trioxide complex at pH greater than 7. Appellant complains that this specific claim is no protection for the broad invention he has disclosed and claims in some of the appealed claims.

The complexity of issues requires that we outline briefly the disclosure and claims of appellant's application and of the Arth et al. patent and set the legal problem in its factual background.

Appellant's Disclosure

Appellant asserts as his broad invention the oxidizing of primary and secondary alcohols, particularly unsaturated alcohols, in alkaline medium with organic base-chromium trioxide complexes. Preferred bases are pyridine, gamma-picoline, beta-picoline, lutidines, quinoline, diethyl formamide and the like. Oxidation is effected by **[***5]** intimately **[*1184]** contacting the alcohol with oxidizing agent in inert solvent. Primary alcohols are oxidized to aldehydes, secondary alcohols to ketones. The specification includes many types of alcohols to which the process is applicable. Over sixty types are disclosed including aliphatic, aralkyl, aralkenyl, aralkinyl alcohols, to name a few, as well as steroid alcohols and steroid derivatives such as pregnanes, cholanes, etc.

Appellant says his process is especially useful in oxidizing certain hydroxy **[**1007]** (-OH) functional groups on steroids to their corresponding keto (=O) groups. For example, 17-position hydroxys may be oxidized to 17-ketos without affecting unsaturated bonds elsewhere in the molecule. The specification includes thirty-one specific examples in which alcohols ranging from cyclopentanopolyhydrophenanthrene derivatives to n-butyl alcohol (allowed claim 7) are oxidized. Included are pregnanes, ergosterols, phenanthrenes, pyrans, benzyl alcohols, propene alcohols, etc.

Claims 8-14, defining appellant's process, set forth specific complex alcohols as follows: [4] claim 8 - 3-acetoxy-11-keto-20-hydroxypregnane; claim 9 - 3,21-diacetoxy-11-keto-17,20-dihydroxypregnane; **[***6]** claim 10 - [*] (8(9),22)-3-acetoxy-7,11-dihydroxyergostadiene; claim 11 - 4b-methyl-7-ethylenedioxy - 1,2,3,4,4a,4b,5,6,7,8,10a - dodecahydrophenanthrene-1,4-diol; claim 12 - 4b-methyl-7-ethylenedioxy-1,2,3,4,4a,-4b,5,6,7,8,10,10a-dodecahydrophe claim 13 - 4b-methyl-7-ethylenedioxy - 1,2,3,4,4a,4b,5,6,7,8,10,10a - dodecahydrophenanthrene-1-one-4-ol; claim 14 - 4b-methyl-7-ethylenedioxy-1,2,3,4,4a,4b,5,6,7,8,10,10a-dodecahydropher In all the aforementioned alcohols, hydroxy groups are oxidized to keto groups in the claimed process.

4 For structural formulae and conventional numbering of steroid nuclei, see Handbook of Chemistry and Physics, 44th Ed. (1962-3), pp. 1946-1971.

Claim 16, supra, is the broadest of claims 15-19. It

is inclusive of all primary and secondary alcohols. Claim 15 differs from 16 only in its definition of the complex former used in preparing the oxidizing agent. It too, therefore, includes all primary and secondary alcohols.

The Arth et al. Patent Disclosure

[1] Although on the double patenting rejection here involved we are concerned only with what this patent claims, in order to understand **[***7]** what it does claim and discuss the opposing arguments on this question, it is necessary to give some consideration to the disclosure of the specification, bearing in mind always that the teachings of that specification (inclusive of its claims) are not prior art with reference to appellant's invention as defined in the claims on appeal, since the **[*1185]** application on appeal and the patent have the same effective filing date. *In re Coleman et al., 38 CCPA 1156, 189 F.2d 976, 90 USPQ 100.* We preface this consideration by quoting the Patent Office position as stated in the solicitor's brief:

> The position of the Patent Office with respect to this ground of rejection is that the instant claims are directed to essentially the same invention as that recited in any of Arth's process claims 9, 10, 11, 12 and 16, and that the two groups of claims differ only in scope. [Emphasis added.]

Arth et al., as does appellant, disclose processes for oxidizing specifically 4b-methyl-dodecahydrophenanthrene-1,4-diol-7-one to 1,4,7-triones. [5] In addition, however, Arth et al. teach processes for isomerizing various triones by alkali treatment to form stereoisomers thereof. The claims define **[***8]** both processes and compounds. Only process claims are germane to the instant appeal, as the solicitor has made clear, since appellant claims processes.

> 5 Such names are too cumbersome for discussion.
> 4b-methyl-dodecahydrophenanthrene-1,4,7-trione is represented structurally, as shown in the patent, thus:
>
> [Graphic omitted. See illustration in original.]
>
> Hereinafter in this opinion, to simplify discussion, such molecule will be referred to simply by variations at the 1, 4, and 7 positions, omitting the long name of the basic 3-ring structure, e.g., 1,4,7-trione as above, or 7-ethylene-dioxy-1-ol-4-one, etc. Also 7-ethylenedioxy will be simply "7-dioxy." (The term "-one" refers, of course, to =0 and "-ol" designates OH, oxidation transforming the latter into the former by removal of a hydrogen atom.)

**[**1008]** Simply stated, Arth et al. teach that 1,4,7-triones are made by oxidizing 1,4-hydroxy compounds in which the 7-keto position is protected by a group R, defined as "a substituent convertible to a keto substituent by hydrolysis." Enol ethers and ketals are such groups; ethylenedioxy is used in all examples (herein "7=dioxy"). Oxidation is effected with an **[***9]** "oxidizing agent," disclosed examples being metal alkoxides and also the pyridine-chromium trioxide complex of appellant's claims. That is the source of the legal problem. The 7-dioxy-1,4-hydroxy starting material is intimately contacted with oxidizing agent to effect reaction. The product is a mixture of completely oxidized 1,4-dione and partially oxidized 1-ol-4-one and 1-one-4-ol. The latter two products may be further oxidized to 1,4-dione by repeating the oxidation process. Hydrolysis removes the 7-dioxy group to give 1,4,7-triones by restoration of the original O=substituent.

**[*1186]** An alternative process involves acylating either the 1- or 4-hydroxy group prior to oxidation; this results in a stereoisomer of the trione obtained by the process first above described.

The claims of Arth et al. considered relevant to this appeal by the examiner and the solicitor are 9-12 and 16. [6] Such claims, abbreviated in conformance with footnote 5, supra, read (we have italicized the oxidizing agent):

> 6 The Patent Office position as to which claims of the Arth et al. patent support the "double patenting" rejection has been one of vacillation. The examiner's final rejection relied on claims 9 and 10 only. After reading the brief on appeal to the board, he cited in his Answer thereto claims 9, 10, 11, and 16. The Board of Appeals referred only to claims 9, 10, and 12, ignoring claims 11 and 16, possibly for what it considered good reason. The solicitor's brief in this court places primary emphasis - indeed suggests we may decide the case - on claim 16 alone, with claim 11 as a close follow-up therefor, these claims being similar; in arguing claim 9, new theories

supported by four new references to literature are presented. As to claims 10 and 12, the brief says "consideration of the propriety of these claims of Arth [et al.] as a basis for the double patenting rejection is deemed unnecessary," adding that "if the Court finds that the instant claims are patentably distinct from the broader patent claims 9, 11 or 16, it is highly unlikely that it would fail to find a patentable distinction between the instant claims and patent claims 10 and 12."

[***10] 9. The process for preparing * * * 1,4,7-trione which comprises reacting * * * 7-ethylenedioxy- * * * 1,4-diol with pyridine-chrominum trioxide complex in pyridine, recovering * * * 7-ethylenedioxy- * * * 1,4-dione from the resulting reaction, intimately contacting said dione with an inorganic base, and hydrolyzing the resulting product by heating with an acid.

10. The process for preparing * * * 1,4,7-trione which comprises reacting * * * 7-thylenedioxy- * * * 1,4-diol with pyridine-chromium trioxide complex in pyridine, recovering * * * 7-ethylenedioxy- * * * 1-ol-4-one from resulting reaction, hydrolyzing the recovered product by heating with an acid, intimately contacting the hydrolyzed product with chromium trioxide, and reacting the resulting oxidized product with an inorganic base.

11. The process for preparing * * * 1,4,7-trione which comprises reacting a member from the [**1009] group consisting of 7-enol ether and 7-ketal derivatives of a compound of the formula

[Graphic omitted. See illustration in original.]

with an oxidizing agent, and hydrolyzing the resulting reaction product by heating with an acid.

[*1187] 12. The process for preparing [***11] a compound of the formula:

[Graphic omitted. See illustration in original.]

which comprises reacting * * * 7-ethylenedioxy- * * * 1,4-diol with acetic anhydride in the presence of pyridine to produce the corresponding 1,4-diol-1-acetate, oxidizing a pyridine solution of the resulting acetylated product with pyridine-chromium trioxide complex, hydrolyzing the resulting oxidized product with potassium carbonate, reoxidizing the resulting hydrolyzed product with pyridine-chromium trioxide complex in pyridine solution, and hydrolyzing the resulting oxidized product by heating with an acid.

16. The process which comprises reacting a compound from the group consisting of 7-enol ether and 7-ketal derivatives of a compound of the formula

[Graphic omitted. See illustration in original.]

with an oxidizing agent to produce the corresponding derivatives of * * * 1,4,7-trione.

A point to note in connection with the ensuing discussion is that claims 11 and 16 recite "an oxidizing agent" - a broad, functional, generic expression inclusive of any oxidizing agent - and that the remaining claims 9, 10, and 12 all specify as the oxidizing agent "pyridine-chromium trioxide complex." [***12] Another point to be noted in this connection is that the board relied only on claims 9, 10 and 12 in affirming the double patenting rejection.

The Relationship between Appellant's and the Patentees' Inventions

The foregoing, as well as consideration of the record and briefs, presents a clear picture of the general situation. Appellant Sarett made an invention relating to the oxidation of primary and secondary alcohols which reside in the oxidizing agent used in the oxidation process, part of his invention or discovery being that the agent functions under alkaline conditions. This invention he claims as a process of "intimately contacting" the alcohol to be oxidized with his agent, which is novel as an oxidizing agent though per se a known material, "at a [*1188] pH in excess of 7.0" (alkaline). Following this first oxidation step, oxidation from the intimate contact being presumed, his process as claimed includes the second step of "recovering" the oxidation product, which appears to be conventional, mere completion of the process to get out the oxidation product, and no part of what Sarett invented. In short, his "process" is the result of discovering a new use for a [***13] known composition of matter, viz., pyridine-chromium trioxide complex. Cf. *35 U.S.C. 100(b)* and *101*.

Sarett was working with others, Arth and Poos, for Merck & Co., Inc. (fn. 2, supra), and with them made other process inventions by which certain new

compounds were made by new processes including an oxidation step. Sarett's **[**1010]** oxidation invention could be, and was, used in some of these new processes to produce new compounds. For example, patent claim 9 is a process involving the four steps of oxidizing recovering the oxidation product, reacting it with an inorganic base, and hydrolyzing with heat and acid. Step one is applicant's oxidation invention.

Patent applications were filed on the same day, back in 1951, by Sarett on his sole invention and by Arth, Poos, and Sarett on their joint inventions and concurrently prosecuted until an application on the joint inventions was allowed and passed to issue, in 1955, while the Sarett application was still meeting with rejection on prior art. For the first time on January 21, 1958, the record discloses, it met with a "double patenting" rejection on the Arth et al. patent and this, six years later, is before us for decision. **[***14]** (Over three and a half years was taken by the appeal to the board and two more by the appeal to us. This is "normal" and certainly not chargeable against applicant.) Rejection on art was still relied on before the board but by it was reversed.

Appellant Sarett insists that the joint inventors claimed only their joint inventions in the reference patent, albeit some of the claims indisputably recite Sarett's oxidation invention as one step in certain claimed processes, and that his oxidation invention as defined in the claims on appeal is not claimed therein.

The Patent Office does not say that there is any claim in the patent which, as written, defines the same invention that Sarett is claiming but argues that nevertheless there is "double patenting" - or would be if the appealed claims were patented.

We will not at this point go into the reasoning of the Patent Office, which in essence asks us to ignore specific process step limitations in the patent claims on the ground that they are "conventional" steps. We think it would be well, on policy grounds, first to face squarely a fact which no one has mentioned but which lurks behind the double [*1189] patenting rejection, **[***15]** no doubt, and possibly motivates a rejection on a legal ground which is at times exceedingly obscure. Certainly it is in this case.

Sarett's oxidizing agents are disclosed in the Arth et al. patent. They are even named in some of the claims as used in one step of multistep processes. That patent having been issued before any patent claiming the Sarett oxidizing process could possibly issue (the time lapse would have been nearly three years at the time of final rejection and is now about nine), if the appealed claims are patented, the patent owner, the common assignee, will have continuing patent rights covering an oxidation process step disclosed in the Arth et al. patent and mentioned in some of its claims long after that patent expires. Another fact which seems to have influenced, if not confused, the Patent Office thinking is that the patent contains claims (e.g., patent claim 16) which dominate the invention of some of appellant's claims calling for "an oxidizing agent" broadly, which claims are supported by a disclosure of such agents which includes appellant's agent.

[2] Now if, by any fair interpretation, it can be said that the reference patent claims [7] the invention **[***16]** on which Sarett's assignee is here seeking another patent, it could be said that allowance of the appealed claims would be an extension of the monopoly of the Arth et al. patent beyond its expiration, the principal supposed evil prevented by the rule against "double patenting." [8] If the patent does **[**1011]** not claim the invention, then we would have the not unusual situation in which, when a patent expires, something disclosed in it happens to be covered by the claims of another patent in common ownership and thus would have no extension of a patent monopoly, but merely a legal continuing monopoly. The exigencies of prosecution commonly compel the issuance of interrelated applications with overlapping disclosures at widely divergent times.

7 [3] It should be clear that the patent could not legally contain a claim to Sarett's sole invention under existing law because it would not have been the invention of the joint patentees. This rule of law forces the filing of distinct applications in many situations resembling that before us and creates complexities and delays which could be avoided under a less rigid statute. Cf. *35 U.S.C. 111*, *116*, and *256*.

8 A wide variety of fact situations appear in cases which have been lumped under the "double patenting" heading. We do not recall a case, and none has been cited, involving facts on all fours with those here but similar situations are not at all uncommon.

[***17] "Double patenting" rejections are a not infrequent cause of patents issuing with claims covering subject matter disclosed in patents issued much earlier [9] and for that reason may do the public a much greater disservice than the evils they are supposed to prevent in that they string out over a longer period the patent protection granted [*1190] on related inventions made at the same time and also delay the disclosure to the public of the technical data contained in related applications growing out of integrated research. On the other hand, no real public injury is likely to result from the issuance of two patents, even on the same invention, at about the same time to a common assignee. [10] If the ultimate results in the instant case are ever regarded by anyone as appalling, it should be remembered what caused the delay - to the public's misfortune - in the issuance of Sarett's patent.

9 See, for example, the fact situations in the numerous cases discussed in this court's opinion in *In re Stanley et al., 41 CCPA 956, 214 F.2d 151, 102 USPQ 234*, especially those in which double patenting rejections were reversed.

10 We are not unaware of the potential divided ownership argument but we think that, realistically, it lacks substance.

[***18] We return to a consideration of the specifics of the double patenting rejection, remembering that the question is whether the Sarett invention of the appealed claims is in effect claimed in the issued Arth et al. patent.

Double Patenting Rejection

The board considered all of appellant's claims to be directed to the same invention claimed in Arth et al. It said (all emphasis ours):

In the present case we are convinced that claims 8 to 19 are not directed to a different invention from that claimed in the Arth et al. patent. The essential feature of the process of claims 9, 10 and 12 of Arth et al. is the oxidation of the 7-ethylene dioxy-dodecahydrophenanthrene-1,4-diols with pyridine-chromium trioxide complex in pyridine. As the Examiner points out, the alkali treatment and the removal of the 7-ethylene dioxide [dioxy] protective group involve merely conventional procedures in this art. It would be expected, indeed, that the dione products of the Arth et al. claims would be subjected to such a treatment. A chemist of ordinary skill in this art would be aware from the Arth et al. claims of the general oxidation applications of the pyridine-chromium trioxide agent employed [***19] in a pH in excess of 7.0, including the applications called for in claims 8 to 19.

Claims 8 to 14 call for the oxidation of hydroxy groups on various dodecahydrophenanthrene and cyclopentanophenanthrene derivatives but in each case the oxidation reaction is of essentially the same character as that of the Arth et al. patent claims. Each involves the oxidation of one oxidation-susceptible hydroxy group without eliminating a double bond in the nucleus or without disturbing groups which might have been oxidation-susceptible in acidic media. In the process of appellant's claims 18 and 19 the oxidation called for may involve any or every compound having, respectively, a phenanthrene and a cyclopentanophenanthrene [**1012] nucleus and, therefore, may involve compounds having substituents or unsaturation of the type called for in the claims of Arth et al. as well as compounds presenting no oxidation problems.

The generic claims 15 to 17 represent an extrapolation of the oxidation process of the Arth et al. claims to all alcohols or all aliphatic alcohols since it would be apparent from the patent that the chromium trioxide - pyridine oxidation claimed as useful in the oxidation [***20] of the patent claims, would be useful in a wide variety of oxidation processes where no particular problem of protecting oxygen-susceptible radicals or bonds exists.

[*1191] Appellant argues that the board erred in considering Arth et al.'s claimed process to be essentially oxidation followed by "conventional" separation steps; that alkaline treatment effects isomerization which is "non-conventional"; and that appellant's claims are "generic" to those of Arth et al. and patentable under the rationale of *In re Stanley et al., 41 CCPA 956, 214 F.2d 151, 102 USPQ 234*. Further, appellant points out that the parent applications of both Arth et al. and his instant application were filed on the same day; that the claims under appeal could not have been asserted by Arth et al. since the latter's disclosure provided no basis therefor; and that in fact appellant is the inventor of the "generic" invention while the co-inventors in Arth et al. are the inventors of the more narrow invention claimed therein.

No simple relationship exists between the claims of Arth et al. and appellant's claims. Some of appellant's

claims are more specific, some more generic to those of Arth et al. Some **[***21]** are hybrid. We must therefore look at each claim and analyze it on its own merits.

[4] We can, of course, read the claims in the light of the specifications which support them. *In re Simmons, 50 CCPA 990, 312 F.2d 821, 136 USPQ 450.* We do this in order to determine what invention is defined by a claim. [5] Having done that, what remains to be decided with respect to each claim of the application is whether it defines an invention which is patentably distinct from any claim of the issued patent. *In re Stanley, et al., supra.*

[6] Our analysis of both the Arth et al. disclosure and appellant's convinces us that the board manifestly erred in rejecting claims 8-10 and 15-19. The former relate to the oxidation of three specific cyclopentanopolyhydrophenanthrenes, none of which is disclosed by Arth et al., let alone claimed. The mere fact that the oxidation of cyclopentanopolyhydrophenanthrenes, as stated by the board, "is of essentially the same character as that of the Arth et al. patent claims" is not controlling. In our view, phenanthrenes, which Arth et al. disclose, and cyclopentanopolyhydrophenanthrenes, which they do not, are distinct classes of compounds and so are **[***22]** the compounds resulting from their oxidation. There is no reference of record on which to rest the view that they are not. We therefore consider claims 8-10 to be patentably distinct from any claim in Arth et al. since no claim in that patent is directed to the oxidation of cyclopentanopolyhydrophenanthrenes, subject matter undisclosed in the patent.

[7] As to claims 15-19, they are generic relative to the Arth et al. claims in their definitions of the classes of alcohols oxidized. Certainly a claim to the genus so defined is not directed to the same subject matter as a claim to the species and we hold claims 15-19 to be "patentably distinct" from any Arth et al. claims. Claims 17 and 19, **[*1192]** furthermore, define classes of alcohols (subgeneric relative to claims 15 and 16) not even disclosed by Arth et al. and, a fortiori, are patentably distinct from the claims therein. Thus claims 15-19 are all deemed to define inventions distinct from any inventions defined in the claims of Arth et al. and to be patentable thereover.

[8] We cannot agree with the board's reasoning because, instead of considering **[**1013]** whether the claims of the patent are directed to **[***23]** the subject matter of the appealed claims, it treats the patent claims like a prior art reference and says, in effect, a chemist reading those claims would be aware that the pyridine-chromium complex used under alkaline conditions, referred to in the claims, would have "general oxidation applications," including those specifically claimed by appellant and also as claimed generically by appellant. We are not here concerned with what one skilled in the art would be aware from reading the claims but with what inventions the claims define.

It remains to consider appellant's claims 11-14.

Claim 11

Claim 11 defines the process whereby 7-dioxy-1,4-diol is oxidized with pyridine-chromium trioxide complex at pH in excess of 7.0 to produce a mixture of 1,4-dione, 1-one-4-ol, and 1-ol-4-one, the three products being recovered from the reaction mixture.

The board's view appears to have been that Arth et al. really claim the same invention in any one of claims 9, 10, and 12. Of these claim 9 is, according to the solicitor, the most similar [11] so we shall discuss it. The Patent Office regards it as "representative of these claims and in effect says if we disagree as to claim 9 it is **[***24]** unnecessary to consider 10 and 12.

11 Cf. fn. 6, supra.

Arth et al. claim 9, which we have set forth earlier, defines a four-step process including not only oxidation and recovery, as in appealed claim 11, but two other steps: (1) treatment of recovered 1,4-dione with inorganic base and (2) hydrolyzing the resulting recovered product by heating with acid. The latter step in fact removes the 7-ethylene-dioxy protective group, as appellant admits.

The board's idea, shown by the above quotation from its opinion, was that the "essential feature" of patent claim 9 is the oxidation with appellant's oxidizing agent and that steps (1) and (2) "involve merely conventional procedures" which one of ordinary skill in this art would expect to be applied to the dione product of the oxidation step. By this thinking the board reduces the patent claim to a two-step process and thus equates it with appealed claim 11, both processes being equivalent. We find the reasoning unsound for various reasons.

**[*1193]** Appellant points out that the inorganic base

treatment in the patent claim is to effect isomerization which is not conventional and also that the use of hydrolysis step (2) **[***25]** is not "conventional" in the process of the claim since one might desire to leave the protective ethylenedioxy group on the phenanthrene nucleus, citing an instance of where this is done in the art. The board, as we have pointed out before, cites nothing to show what is "conventional."

As to the conventionality of step (1), we do not agree with the board. Although it is not quite clear from the Arth et al. disclosure when alkali alumina (inorganic base) treatment is used for isomerization and when it is used simply as a recovery technique, it is clear that 1,4-dione per se is not treated with alumina except to effect isomerization. Furthermore, claim 9 of Arth et al. requires that 1,4-dione first be recovered and only thereafter is it intimately "contacted" (i.e., allowed to react) with inorganic base. Clearly this is not for the purpose of separating 1,4-dione from anything, i.e., for recovery, and must be for isomerization. On this record we cannot equate the inorganic base treatment step of claim 9 of the patent with the recovery step of appealed claim 11 so as to make it "conventional" on the assumption that "recovery" is conventional. Claim 11, in our opinion, is patentably **[***26]** distinguishable from claim 9 of Arth et al. and not rejectable on that claim.

Contrary to the board, which relied on Arth et al. claims 9, 10, and 12, the solicitor has placed principal reliance on **[**1014]** their claim 16, which would seem to show a hesitancy to rely on the board's reasoning, considering also that the board did not even mention claim 16 (or claim 11, the solicitor's second line of defense).

Claim 16 differs from appealed claim 11, first, in its definition of the alcohol to be oxidized. Claim 11 specifies (see fn. 5) 7-dioxy-1,4-diol which is included within claim 16 in the term "7-ketal derivatives"; but claim 16 also includes "7-enol ether" derivatives. Next, the oxidation products are specified in claim 11 to be three named compounds; in claim 16 they are broadly defined as derivatives of 1,4,7-trione, inclusive of the three but any one or more would be within the claim. Claim 16 is a single step process claim to "reacting * * * to produce." Claim 11 is a two-step process to "preparing" by "contacting" and "recovering." Perhaps the differences above recited are only such differences in scope as not to avoid "double patenting" but we do not have to decide **[***27]** that question because of another major difference between the claims in defining the oxidizing agent used in the process.

Arth et al. claim 16 calls for "an oxidizing agent" rather than for the specific agent of claim 11, "pyridine-chromium trioxide complex at a pH in excess of 7.0."

**[*1194]** The situation is that the oxidizing agent used in the process is claimed generically [12] in the patent in the broadest possible terms as "an oxidizing agent" and as specifically as possible in the application at bar by naming a single oxidizing agent - "pyridine-chromium trioxide complex" - "at a pH in excess of 7.0." Clearly these two claims, to broad genus and narrow species respectively, are patentably distinct. The solicitor admits the correctness of this broad genus and narrow species characterization by making it himself. Nevertheless, he flatly contends that "patent claim 16 and instant claim 11 are directed to the same invention."

12 Commissioner Paine correctly said in Ex parte Ewart, 1880 CD 78:

> "The term 'generic,' in its application to inventions, has not an absolute but only a relative signification. An invention which is generic in its relation to a class of inventions which it embraces as species may itself be specific in its relation to a broader class in which it is included."

**[***28]** [10] The solicitor first argues that "Claim 16 is readable on the single step of oxidizing" the 7-dioxy-1,4-diol of Sarett claim 11, but it is elementary that readability of a claim on the subject matter of another claim (domination) is neither determinative of the double patenting issue nor demonstrative that claims are directed to the same invention. As Stringham said in his "Double Patenting" many years ago, p. 207:

> One of the simplest, clearest, soundest, and most essential principles of patent law, is that a later invention may be validly patented, although dominated by an earlier patent, whether to the same or to a different inventor.

He also said something else worth remembering anent the issues in this case, p. 209:

> The difficulty which American courts, throughout

nearly their whole history, have had in understanding the application to patent law of the elementary logic of dominance and subordination, genus and species, goes back to the primitive thought that an "invention" upon which the patent gives protection is something tangible. The physical embodiment or disclosure, which, in itself is something tangible, is confused with the definition or claim to the inventive [***29] novelty, and this definition or claim or monopoly, also sometimes called "invention" in one of that word's meanings, is not something tangible, but is an abstraction. Definitions are always abstractions. This primitive confusion of "invention" in the sense of physical embodiment with "invention" in the sense of definition of the patentable amount of novelty, survives [**1015] to the present day [1933], not only in the courts, but among some of the examiners in the Patent Office.

In patent law there is no possibility of clear thinking until it is understood that an "invention" as protected by a patent is an abstraction, an idea of means.[Our emphasis.]

And on page 223 the same author reiterates:

Springing from the failure to recognize the abstract nature of an "invention" as protected by a patent arises the confusion caused by the words "covered," "embraced," and "protected." The tribunals fail to remember that inventions [*1195] like other phenomena fall into genera, and that the genus may be patented. Exactly here lies a mass of judicial and administrative error of perhaps greater magnitude than any other mass of error in the whole field of patent law. No useful [***30] thinking can be done on the question of double patenting law, as applied to claims of different scope, until this confusion about genus and species is removed.

This author's words are worth heeding. He has devoted more published thought to "double patenting" problems than any other scholar in the field.

[11] In urging identity of the invention claimed in claims 16 and 11, the solicitor next attempts to rely on the fact that "Arth [et al.] discloses the use of that specific oxidizing agent," meaning appellant's agent. But the patent also discloses a whole class of other oxidizing agents - metal alkoxides - and appellant's pyridine-chromium trioxide complex is disclosed as a possible alternative to their use. Here the solicitor is falling into the very fault of reasoning pointed out by Stringham a quarter century ago, confusing the disclosure with the definition of the claim, or asking us to. The mere inclusion in the supporting disclosure for the generic claim to all oxidizing agents of appellant's specific oxidizing agent does not convert the generic claim to a claim to the species. Nor, may we add, does the recitation of appellant's agent as used in one step of some [***31] of the patentees' other four- and five-step process claims. This second argument is, therefore, without weight.

Finally, the solicitor says:

* * * appellants [sic] admit that Arth et al. were the inventors of appellants' [sic] oxidation reaction in conjunction with other reaction steps (Br-28), [so] it is evident that patent claim 16 and instant claim 11 are directed to the same invention. [Original emphasis.]

The wrong words have been italicized by the solicitor. The important words from the supposed "admission" are "in conjunction with other reaction steps" and when they are heeded and taken in context there is no "admission" whatsoever. There is such a transparent effort to turn a plain statement into something it is not that we deem it desirable to show what appellant's brief actually said:

Likewise here as in Stanley et al. appellant stresses that he is the inventor of the generic oxidation reaction, which therefore could not have been claimed by Arth et al. Arth et al. were the inventors of the specific "improvement" claimed in their patent comprising the process of producing the novel triketo compounds of their invention by successive stages of reaction [***32] applied to a specific starting material, including appellant's oxidation reaction in conjunction with other reaction steps.

We think this speaks for itself, that the "admission" relied on, to be charitable, is the nonexistent product of an overwrought imagination and we therefore find no support in this argument for the contention [*1196] that the claims are for the same invention. We will not sustain the rejection of claim 11 on the ground of "double patenting."

[**1016] Claims 12, 13, and 14

Claim 12 defines the two-step process of (1) oxidizing 1,4-diol-1-acetate with pyridine-chromium trioxide complex at pH in excess of 7.0 to produce

1-ol-4-one-1-acetate and (2) recovering it.

Claims 13 and 14 define, respectively, the oxidation, with the same oxidizing agent as in claim 12, of 7-dioxy-1-one-4-ol and 7-dioxy-1-ol-4-one to produce the corresponding 1,4-dione and the recovery thereof.

The Patent Office makes the same argument based on Arth et al. claim 16 (and secondarily claim 11) as to these claims which it made on appealed claim 11 without distinguishing between them. We reject that argument for the reasons we have stated.

As to Arth et al. claims 9, **[***33]** 10, and 12 on which the board chose to rely, the solicitor rested his case on patent claim 9 saying that if the court held against him as to that claim he thought it "highly unlikely that it would fail to find a patentable distinction between the instant claims and patent claims 10 and 12." We give the prophet his due but in doing so we state it to be our opinion that patent claim 12 is the most relevant to appealed claim 12 and patent claim 10 is the most relevant to appealed claims 13 and 14. However, each of the appealed claims defines an oxidation with Sarett's specific oxidizing agent followed by a conventional "recovery" of any desired and undefined kind. Patent claims 10 and 12 by contrast define five-step processes involving isomerization of one of the recovered products as in the case of claim 11, fully discussed above. We find in these facts more than enough to convince us that "patentable distinction" exists.

We therefore reverse all rejections predicated on "double patenting."

Indefiniteness Rejection

The examiner said in his answer [all emphasis ours]:

These latter claims [15-19] are so broad as to be indefinite in the use of the indefinite articles "an" **[***34]** and "a" to define the alcohol reactants. Admittedly, the disclosure of operative schools [alcohols] is broad, however, interfering oxidation sensitive groups such as sulfides, sulfoxides, olefinic, acetylenic, cyano, carbamyl, and isocyanate are not shown to be operative in the herein claimed process. All of these groups are oxidation sensitive and may be preferably oxidized instead of the alcohol groups, and thus rendering the process inoperative. [Cases cited.]

The board said [all emphasis ours]:

The Examiner rules that claims 15 to 19 are indefinite because of the articles "a" and "an" employed to characterize the alcohol oxidized. We understand **[*1197]** this to be a rejection based on the claims' failure to comply with the requirements of *35 U.S.C. 112* because they do not definitely delineate the groups of alcohols to which the claimed process is applicable. Appellant's process is described as being in the oxidation of OH radicals in certain types of compounds - particularly the alcohols having acid-sensitive substituents or unsaturated bonds which cannot be oxidized under acidic conditions. We find, though, no indication in the claims of the alcohols to which **[***35]** the process is applicable or for which it has particular advantages. Undoubtedly, the process has advantages for numerous alcohols. Undoubtedly, also, there are alcoholic compounds, bearing competitively reactive groups, with which the pyridine-complex might produce some results but not the oxidation advantages in the production of the corresponding carbonyl compound on which appellant predicates patentability.

* * * 15 to 19 are not definite as to the alcohol 12 to 19 are not definite as to the alcohol compound oxidized. Appellant's specification contributes to the indefiniteness of the compounds by indicating * * * that the **[**1017]** "primary and secondary alcohols reduced [oxidized] by the methods of the present invention can be unsubstituted alcohols or alcohols containing substituents such as halo, amino, nitro carbonyl, sulfonic acid groups and the like". This redefinition not only distorts the meaning of the term "alcohol" * * * but also leaves in doubt what other radicals are included in the term "and the like".

On reconsideration the board added:

Appellant's claims 15 to 19, however, do not exclude any substituents on the alcohol radical which may be considered **[***36]** the "like" of "substituents such as halo, amino, nitro carbonyl sulfonic acid groups * * *" and appellant's specification includes polyhydric alcohols among the materials that he may oxidize so that the term "alcohol" is not interpreted as being a "monohydric alcohol." It is doubtful whether the claims exclude compounds with a tertiary alcohol group in addition to a primary or secondary alcohol group.

Apparently the board had in mind two separate bases of rejection under *35 U.S.C. 112*: indefiniteness, in that

appellant "distorts the meaning of" or redefines the term "alcohol"; and undue breadth, in that appellant fails to set out the specific classes of alcohols to which his process is applicable.

As we view appellant's disclosure and claims, the invention is a broad one, wherein primary and secondary alcohols generally are oxidized at the hydroxy group. Use of a mild oxidizing agent in alkaline medium prevents interference with unsaturated bonds or acid-sensitive groups elsewhere in the alcohol molecule. The process is in no way limited to oxidation of alcohols having such bonds or groups but is particularly applicable thereto. Neither the examiner nor the board seems to [***37] disagree with this, the examiner saying that "the disclosure of operative alcohols is broad" but refusing, nevertheless, to allow commensurately broad claims because appellant has not shown that certain easily oxidizable groups not excluded by the claims are "operative." Similarly, the board acknowledges that the "process has advantages [*1198] for numerous alcohols" but nevertheless sustains the examiner.

Appellant argues that disclosure of over sixty operative classes of alcohols, and thirty-one specific examples, is ample basis to support broad claims; that neither the examiner nor the board support their skepticism about operability with specific inoperative examples; and that appellant does not distort the definition of "alcohol."

We agree with appellant. With respect to redefining "alcohol," appellant's brief states:

There are three classes of alcohols: primary, secondary and tertiary.Primary alcohols are characterized by the fact that the carbon atom bearing the hydroxyl substituent is also attached to two hydrogen atoms. In secondary alcohols this carbon atom is attached to only one hydrogen atom. In tertiary alcohols there are no hydrogen atoms attached to the [***38] carbon atom bearing the hydroxyl substituent. Obviously then appellant's definition of primary and secondary alcohols as "having at least one hydrogen atom attached to the carbon atom bearing the hydroxyl substituent" does not distort the definition of primary and secondary alcohols in any way.

Appellant's contention [is] that the alcohols which may be oxidized by the process of his invention can be substituted or unsubstituted and similarly does not distort any definition of alcohols acceptable to those skilled in the art. "Unsubstituted" means that the hydrogen atoms attached to the carbon atom of the alcohol molecule are not replaced with other functional groups. "Substituted" means that at least one hydrogen atom is replaced with a functional group. Butanol is an unsubstituted [**1018] alcohol, whereas 3-chlorobutanol is a substituted alcohol. This is the accepted meaning of these terms in the art.

As we said at the beginning, in appellant's claims, the phrase "an alcohol having at least one hydrogen atom attached to the carbon atoms bearing the hydroxyl substituent" means primary and secondary alcohols. [13] The specification states that such alcohols may be "substituted" [***39] and may be "polyhydric." We see nothing unconventional about such terminology. [14] Thus the claims are not indefinite.

13 Hackh's Chemical Dictionary, 3d Ed., supports us. The presence of other -OH groups, rendering the alcohol polyhydric, does not make the alcohol any less "primary" or "secondary." Further, contrary to the board, we consider it immaterial that appellant's claimed alcohols include those containing a tertiary alcohol group.

14 In fact, The Condensed Chemical Dictionary, 4th Ed., p. 21, in defining "alcohol" states, inter alia, "In general the ending -01 in the name of an organic compound signifies the presence of an OH radical, and alcoholic properties are to be expected, although they may be markedly modified by other elements present in the molecule." [Emphasis ours.] Thus to suggest that substitution of alcohols by other elements renders the compound no longer an alcohol would seem erroneous.

As to the undue breadth rejection, appellant's brief states [emphasis ours]:

We note further that R. Macy in "Organic Chemistry Simplified," Chemical Publishing Co., 1943, in defining alcohols, at p. 79, states "The hydroxy (OH) groups attached to the carbon [***40] chain are called alcohols. The compound described in the preceding section [CH(3)CHOHCHCH(3)CHClCH(2)CH(3)] is therefore known to the organic chemist as 3-methyl,4-chlorohexanol-2 * * *." We note [*1199] that even in defining alcohol, the author uses as an example a substituted alcohol.

"Polyhydric" is conventional terminology, Hackh defining polyhydric alcohols as those with an indeterminate number of hydroxy groups, thus R(OH)(x).

Appellant in his specification * * * has amply illustrated both substituted and unsubstituted primary and secondary alcohols which may be oxidized by the process of the invention. The application names over sixty such alcohols to which the invention is applicable * * *.

The alcohols thus listed include both primary and secondary monohydroxy alcohols, polyhydroxy alcohols, saturated and unsaturated alcohols, aralkyl alcohols, including those in which the aryl group is substituted with nitro, hydroxy and alkoxy groups, alicyclic alcohols, polycyclic alcohols, heterocyclic alcohols, terpine alcohols and steroid alcohols, including those in which the alcohol group is attached directly to the cyclopentanophenanthrene ring and those in which [***41] it is attached to a side chain on the ring.

In addition to the above, appellant concludes his specification with thirty-one specific examples * * * illustrating the application of his novel method to different primary and secondary alcohols. These include simple primary alkanols such as n-butyl alcohol and also more complex polyfunctional primary and secondary alcohols including pregnane derivatives, sex hormones, phenanthrene compounds, substituted and unsubstituted heterocyclic alcohols, bile acid derivatives, aralkenols and substituted and unsubstituted aralkanols.

[12] We believe appellant's claims are supported by the specification. Broad inventions can be defined only by broad claims. *In re Sus et al., 49 CCPA 1301, 306 F.2d 494, 134 USPQ 301.* As stated by this court in *In re Cavallito et al., 48 CCPA 711, 282 F.2d 357, 127 USPQ 202,*

The question whether a broad claim to an invention in the field of chemistry is sufficiently supported by the compounds named and examples given in an application has been frequently considered by this court. [**1019] As was said in *In re Shokal et al., 44 CCPA 854, 242 F.2d 771, 113 USPQ 283*:

The decisions do not however fix [***42] any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases.

The mere fact that a claim covers a large, or even an unlimited number of products, does not necessarily establish that it is too broad.

[13] We consider the disclosure here of over sixty classes of alcohols and thirty-one specific examples of diverse alcohol types to be adequate basis for appellant's claims.

Both the examiner and the solicitor list various oxidizable substituents including sulfide, sulfoxide, olefinic, acetylenic, etc., which they say if present on an alcohol may render the claimed process "inoperable." We see no basis for such conclusion. Even if such substituents be present, it does not follow that the hydroxy group will not be oxidized, which is all the claims require.

[14] In any event, the mere possibility of inclusion of inoperative substances does not prevent allowance of broad claims. The board [*1200] has so held in *Ex parte Lilienfeld, 44 USPQ 174, Ex parte Pechukas, 94 USPQ 390,* and *Ex parte Friedman, 136 USPQ 381,* all cited by appellant. [***43] If they are so broad as to be vulnerable, no one but the patentee will suffer from it.

It is certainly not incumbent on an applicant who has made a broad process invention and supported it by an adequately broad disclosure to demonstrate the operativeness of every substance falling within the scope of the broad claims to which he is entitled. In the instant case the research to do this would quite evidently be endless.

[15] The function of claims is to point out the invention and define the scope of the monopoly, not to exclude substances which are possibly of no use in practicing the invention.

We do not consider the claims unduly broad and reverse the indefiniteness rejection.

The decision of the board is reversed.

WORLEY, C.J., concurs in result.